

Policy and Procedure

| | |
|--|--|
| PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCNEU029.0825 | NEUROMUSCULAR DRUGS BOTULINUM TOXIN See Appendix A for medications covered by policy |
| Effective Date: 10/1/2025 | 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 (JH) |
| Original Effective Date: 09/19 | P&T Committee Meeting Date: 06/19, 08/19, 10/19, 12/19, 02/20, 06/20, 08/20, 12/20, 02/21, 06/21, 08/21, 08/22, 08/23, 12/23, 10/24, 02/25, 08/25 |
| 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.

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:

For initial authorization, must meet specific criteria outlined below for each botulinum toxin product:

1. OnabotulinumtoxinA (Botox®) may be covered for the following indications when criteria are met:
 - a. Chronic migraine headaches in adults when all the following is met:
 - i. Documentation of at least 15 headache days per month with headaches lasting four hours or longer

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCNEU029**

**NEUROMUSCULAR DRUGS
BOTULINUM TOXIN**
See [Appendix A](#) for medications covered by policy

- ii. Documentation of trial and failure, intolerance, or contraindication to at least TWO of the following classes used for migraine prevention. Trial and failure is defined as inadequate response following a minimum three months of consistent use.
 - 1) Antidepressants (e.g., amitriptyline, venlafaxine)
 - 2) Beta-blockers (e.g., metoprolol, propranolol, timolol)
 - 3) Antiepileptics (e.g., divalproex, valproate, topiramate)
 - 4) Calcitonin Gene Related Peptide (CGRP) receptor antagonists (e.g., Aimovig®, Emgality®, Nurtec ODT®)
- iii. For patients established on a Calcitonin Gene Related Peptide (CGRP) receptor antagonist for migraine prophylaxis, combination therapy with Botox® may be considered medically necessary if the following criteria are met:
 - 1) The patient has been established on, and adherent to, CGRP prophylaxis therapy (e.g., Aimovig®, Emgality®, Ajovy®) for at least six months and has a documented improvement in frequency and/or severity of migraine headaches
 - 2) Patient continues to have at least 15 headache days per month with headaches lasting four hours or longer, despite use of CGRP prophylaxis monotherapy
- 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. Severe axillary or palmar hyperhidrosis in adults after all the following are met:
 - i. Prescribed by or in consultation with a dermatologist
 - ii. Documented trial and failure, intolerance or contraindication to at least a one-month trial topical agents [such as aluminum chloride hexahydrate (Drysol®) and glycopyrronium tosylate (Qbrexza®). Note these medications may also require prior authorization].
 - iii. Hyperhidrosis has led to secondary medical issues (such as skin infections, psychosocial problems, or issues severely affecting daily functioning).
- f. Overactive bladder in adults with:
 - i. Symptoms of urge urinary incontinence, urgency, and frequency
 - ii. Documented at least one month trial and failure, intolerance, or contraindication to an anticholinergic medication (e.g., oxybutynin, tolterodine) or beta-3 adrenoceptor agonist (e.g., mirabegron)
- g. Urinary incontinence in patients at least five years of age:

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCNEU029**

**NEUROMUSCULAR DRUGS
BOTULINUM TOXIN**
See [Appendix A](#) for medications covered by policy

- i. Due to detrusor over activity related to a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
 - ii. Documented at least one month trial and failure, intolerance, or contraindication to an anticholinergic medication (e.g., oxybutynin, tolterodine) or beta-3 adrenoceptor agonist (e.g., mirabegron)
 - h. Excessive salivation due to advanced Parkinson's disease
 - i. Hemifacial spasm
 - j. Chronic anal fissure in adults when all the following is met:
 - i. Prescribed by, or in consultation with, a gastroenterologist or colorectal surgeon
 - ii. Documentation of trial and failure, intolerance, or contraindication to at least six weeks of therapy with either topical nitrates or topical calcium channel blockers
 - iii. The use of Botox® in combination with sphincterotomy or anal advancement flap is not considered medically necessary and will not be covered
 - k. Spastic dysphonia (laryngeal dystonia) in adults for adductor type when prescribed by, or in consultation with, a specialist in laryngology
 - l. Achalasia in patients ineligible for definitive treatments, such as pneumatic dilation, surgical myotomy or peroral endoscopic myotomy (POEM)
 - i. The use of Botox® in combination with pneumatic dilation is not considered medically necessary and will not be covered
 - m. Oromandibular dystonia in adults (such as jaw closure dystonia and Meige syndrome)
 - n. Focal hand dystonia in adults (such as writer's cramp)
- 2. AbobotulinumtoxinA (Dysport®) may covered for the following indications:
 - a. Upper and lower limb 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-ianm (Daxxify®) may be covered for the following indications:
 - a. Cervical dystonia in adults

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCNEU029**

**NEUROMUSCULAR DRUGS
BOTULINUM TOXIN**
See [Appendix A](#) for medications covered by policy

Reauthorization:

1. For onabotulinumtoxinA (Botox®) monotherapy or combination therapy with CGRP agent for prophylaxis of chronic migraine headaches: documentation of a 30% reduction in headache days from baseline.
2. All other reauthorization requests for botulinum toxin products require documentation of successful response to therapy.

For indications not listed above, the requested medication must be FDA approved for the intended use or medical rationale must be submitted in support of therapy (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines). Coverage will be considered on a case-by-case basis.

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.

AGE RESTRICTIONS:

N/A, except where noted

PRESCRIBER RESTRICTIONS:

N/A, except where noted

COVERAGE DURATION:

Initial authorization and reauthorization will be approved for one year

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® (abobotulinumtoxinA)

- 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

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCNEU029**

**NEUROMUSCULAR DRUGS
BOTULINUM TOXIN**
See [Appendix A](#) for medications covered by policy

POSITION STATEMENT:

The policy criteria was developed based on 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., DrugDex, AHFS).

Migraine Headache Prophylaxis

The [2018 American Headache Society \(AHS\) Consensus Statement](#) uses the International Classification of Headache Disorders definition of chronic migraines:

1. Migraine-like or tension-type-like headache on ≥ 15 days/month for >3 months that fulfill criteria 2 and 3
2. Occurring in a patient who has had at least 5 attacks fulfilling criteria B-D for migraine without aura* and/or criteria B and C for migraine with aura[†]
3. On ≥ 8 days/month for >3 months, fulfilling any of the following:
 1. Criteria C and D migraine without aura
 2. Criteria B and C for migraine with aura
 3. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative
4. Not better accounted for by another diagnosis

Migraine Features

| *Migraine without aura | †Migraine with aura |
|---|--|
| B. Headache attacks lasting 4-72 hr (untreated or unsuccessfully treated) C. Headache has at least two of the following four characteristics: <ul style="list-style-type: none"> • unilateral location • pulsating quality • moderate or severe pain intensity • aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs) D. During headache at least one of the following: <ul style="list-style-type: none"> • nausea and/or vomiting • photophobia and phonophobia | B. One or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> • visual • sensory • speech and/or language • motor • brainstem • retinal C. At least three of the following six characteristics: <ul style="list-style-type: none"> • at least one aura symptom spreads gradually over ≥ 5 minutes • two or more aura symptoms occur in succession • each individual aura symptom lasts 5-60 minutes¹ • at least one aura symptom is unilateral² • at least one aura symptom is positive³ • the aura is accompanied, or followed within 60 minutes, by headache |

The 2021 American Headache Society (AHS) Consensus Statement recommends preventive treatment to be initiated when any of the following occurs¹²:

- Attacks significantly interfere with patients' daily routines despite acute treatment
- Frequent attacks (≥4 monthly headache days)
- Contraindication to, failure, or overuse of acute treatments, with overuse defined as:
 - 10 or more days per month for ergot derivatives, triptans, opioids, combination analgesics, and a combination of drugs from different classes that are not individually overused
 - 15 or more days per month for non-opioid analgesics, acetaminophen, and nonsteroidal anti-inflammatory drugs
- Adverse events with acute treatments
- Patient preference

Treatments with established efficacy for migraine prophylaxis include antiepileptic drugs (i.e., divalproex sodium, valproate sodium, topiramate), beta-blockers (i.e., metoprolol, propranolol, and timolol), candesartan, tricyclic antidepressants (i.e., amitriptyline, nortriptyline), serotonin-norepinephrine reuptake inhibitors (i.e., venlafaxine, duloxetine), onabotulinumtoxinA, and calcitonin gene-related peptide (CGRP) receptor antagonists [i.e., erenumab (Aimovig®), fremanezumab (Ajovy®), eptinezumab (Vyepti®), atogepant (Qulipta®) and galcanezumab (Emgality®)].¹³

CGRP receptor antagonists are a newer class of medications indicated for migraine prophylaxis. The clinical trials for the prophylaxis CGRP agents excluded patients that were currently using botulinum toxin. There is limited clinical information to support use of combination therapy. The AHS 2021 statement notes that the combination of botulinum toxin and CGRP receptor antagonists is probably effective.¹²

Chronic Anal Fissure

The [2021 American College of Gastroenterology guidelines](#) outline the diagnosis and management of chronic anal fissure. They define anal fissure as an “ulcer-like, longitudinal tear in the midline of the anal canal” and define chronic as lasting more than 8-12 weeks with edema and fibrosis⁷.

Treatment typically consists of topical agents targeting the relief of spasms, such as topical nitrates (e.g., 0.2% nitroglycerin ointment applied twice for 6-8 weeks), and topical calcium channel blockers (e.g., 2% diltiazem applied twice daily for 6–8 weeks). While these therapies are minimally invasive and typically inexpensive, the rate of healing is considered only marginally better than placebo for nitrates and there is “insufficient data to conclude whether [topical CCBs] are superior to placebo.”⁷ Botulinum toxin has healing rates superior to placebo (60-80%) and

patients may be retreated on relapse with similar healing rates. There is no consensus protocol for dosing of botulinum toxin or injection technique. Patients considered medical refractory to these treatments should be referred for surgical evaluation. Lateral internal sphincterotomy (LIS) is preferred over manual anal dilation due to better outcomes and less incontinence adverse effects. However, there is still a risk of incontinence, so topical and injectable therapies continue to be used, despite better efficacy with LIS.

American College of Gastroenterology treatment recommendations for chronic anal fissures⁷:

- Local application of a calcium channel blocker should be the initial medical treatment (strong recommendation, low quality of evidence)
- Botulinum toxin A injections may be attempted in patients whom CCB fails or as an alternative option to CCB (conditional recommendation, low quality of evidence)
- LIS is the surgical treatment of choice for chronic anal fissures that do not heal with nonsurgical measures (strong recommendation, high quality of evidence)

The [American Society of Colon and Rectal Surgeons Guidelines](#) recommendations for chronic anal fissures¹¹:

- May be treated with topical nitrates, although headache symptoms may limit their efficacy (strong recommendation, moderate-quality evidence)
- Compared with topical nitrates, the use of calcium channel blockers for chronic anal fissures has a similar efficacy, with a superior side-effect profile, and can be used as first-line treatment (strong recommendation, moderate-quality)
- Botulinum toxin has similar results compared with topical therapies as first-line therapy and modest improvement in healing rates as second-line therapy following failed treatment with topical therapies (strong recommendation, moderate-quality evidence)
- Lateral internal sphincterotomy (LIS) may be offered in selected pharmacologically naive patients with chronic anal fissure (strong recommendation, high-quality evidence)
- LIS is the treatment of choice in selected patients without baseline fecal incontinence [FI] (strong recommendation, high-quality evidence)
- The addition of an anocutaneous flap to botulinum toxin injection or to LIS may decrease postoperative pain and allow for primary wound healing (weak recommendation, low-quality evidence)
- Short-term outcomes of repeat LIS or botulinum injection for recurrent anal fissure have shown good healing rates with a low risk of FI, but the data are limited and require further study (weak recommendation, low-quality evidence)

Achalasia

Achalasia is a rare mobility disorder of the esophagus and can lead to gastrointestinal issues such as progressive dysphagia to solids and liquids, heartburn, chest pain, regurgitation, and varying degrees of weight loss or nutritional deficiencies. [The American College of Gastroenterology \(ACG\) Clinical Guidelines: Diagnosis and Management of Achalasia](#) recommends botulinum toxin as first-line therapy for patients with achalasia that are unfit for definitive therapies [i.e., pneumatic dilation, surgical myotomy or peroral endoscopic myotomy (POEM)].

Oromandibular dystonia

Oromandibular dystonia (OMD) is a rare focal dystonia affecting the lower half of the face and jaw. Etiology may be idiopathic or secondary. There are different subtypes such as jaw-closing, jaw deviating or it can occur along with other dystonias such as in Meige syndrome. The [American Academy of Oral Medicine Clinical Practice Statement on oromandibular dystonia](#) notes that management of OMD may include botulinum toxin injections, physical/speech therapy, massage, biofeedback, acupuncture, occlusal appliances, pharmacologic therapies (e.g., anticholinergics) and surgery.¹⁴ The majority of rial data evidence comes from small, open-label clinical trials and observational studies in jaw-closure dystonia.

Spastic dysphonia

The [American Academy of Otolaryngology-Head and Neck Surgery Foundation guidelines for dysphonia](#) state that botulinum toxin should be offered for spasmodic dysphonia or laryngeal dystonia. The guidelines notes this is based on limited data from randomized controlled trials.¹⁶

Retrograde cricopharyngeal dysfunction

Retrograde cricopharyngeal muscle dysfunction is a newly described syndrome of secondary cricopharyngeal muscle hypertonicity. It was first described systematically in 2019. Air introduced into the esophagus with swallowing/eating is unable to escape as the cricopharyngeus muscle, a sphincter muscle that sits at the top of the esophagus, is unable to relax resulting in esophageal distention and eventually gastric distention. The gas is most often relieved with flatulence. Individuals have the sensation of being unable to burp. Other symptoms can include chest pain/bloating, gurgling noises, excessive flatulence and difficulty vomiting¹⁹. Current evidence for use of botulinum toxin comes from retrospective reviews, case series and case reports. Often the botulinum toxin injections were all provided by the same surgeon/clinic in these reports. This literature does highlight that botulinum toxin is currently the treatment being tried for this condition; however, there is no high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines to support its use (efficacy and safety).

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCNEU029**

**NEUROMUSCULAR DRUGS
BOTULINUM TOXIN**
See [Appendix A](#) for medications covered by policy

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.

CPT/HCPCS Codes

| All Lines of Business Except Medicare | |
|---------------------------------------|---|
| Prior Authorization Required | |
| 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., chemodenevation 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 | Chemodenevation of internal anal sphincter |
| 52287 | Cystourethroscopy, with injection(s) for chemodenevation of the bladder |
| 64611 | Chemodenevation of parotid and submandibular salivary glands, bilateral |
| 64612 | Chemodenevation of muscle(s); muscle(s) innervated by facial nerve, unilateral (e.g., for blepharospasm, hemifacial spasm) |
| 64615 | Chemodenevation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine) |
| 64616 | Chemodenevation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., for cervical dystonia, spasmodic torticollis) |
| 64617 | Chemodenevation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed |
| 64642 | Chemodenevation of one extremity; 1-4 muscle(s) |
| 64643 | Chemodenevation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure) |

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCNEU029**

**NEUROMUSCULAR DRUGS
BOTULINUM TOXIN**
See [Appendix A](#) for medications covered by policy

| | |
|---|---|
| 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 |
| <p>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.</p> | |
| 31599 | Unlisted procedure, larynx |
| 43499 | Unlisted procedure, esophagus |
| 64999 | Unlisted procedure, nervous system |

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.
6. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice (2018). Available at <https://headachejournal.onlinelibrary.wiley.com/doi/epdf/10.1111/head.13456> (accessed on February 20, 2025).

7. Wald A, Bharucha AE, Limketkai B, *et al.* ACG Clinical Guidelines: Management of Benign Anorectal Disorders. *Am J Gastroenterol.* 2021 Oct 1;116(10):1987-2008.
8. Shao WJ Li GC, Zhang ZK. Systematic review and meta-analysis of randomized controlled trials comparing botulinum toxin injection with lateral internal sphincterotomy for chronic anal fissure *Int J Colorectal Dis.* 2009 Sep;24(9):995-1000.
9. Sileri P, Stolfi VM, Franceschilli L *et al.* Conservative and surgical treatment of chronic anal fissure: prospective longer term results. *J Gastrointest Surg.* 2010 May;14(5):773-80.
10. ACG Clinical Guidelines: Diagnosis and Management of Achalasia, The American Journal of Gastroenterology: September 2020 - Volume 115 - Issue 9 - p 1393-1411 doi: 10.14309/ajg.0000000000000731
11. Davids JS, Hawkins AT, Bhama AR, *et al.* Clinical Practice Guidelines Committee of the American Society of Colon and Rectal Surgeons. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures. *Dis Colon Rectum.* 2023 Feb 1;66(2):190-199.
12. American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice (2021). Available at <https://headachejournal.onlinelibrary.wiley.com/doi/10.1111/head.14153> (accessed on February 20, 2025).
13. American Headache Society Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update (2024). Available at <https://headachejournal.onlinelibrary.wiley.com/doi/full/10.1111/head.14692> (accessed on February 20, 2025).
14. France K, Stoopler ET. The American Academy of Oral Medicine Clinical Practice Statement: Oromandibular dystonia. *Oral Surg Oral Med Oral Pathol Oral Radiol.* 2018 Apr;125(4):283-285.
15. Bhidayasiri R, Fahn S, Weiner WJ, Gronseth GS, Sullivan KL, Zesiewicz TA; American Academy of Neurology. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology.* 2013 Jul 30;81(5):463-9.
16. Stachler RJ, Francis DO, Schwartz SR, *et al.* Clinical Practice Guideline: Hoarseness (Dysphonia) (Update). *Otolaryngol Head Neck Surg.* 2018 Mar;158(1_suppl):S1-S42.
17. Tsui JK, Bhatt M, Calne S, Calne DB. Botulinum toxin in the treatment of writer's cramp: a double-blind study. *Neurology.* Jan 1993;43(1):183-5
18. Dressler D, Adib Saberi F, Rosales RL. Botulinum toxin therapy of dystonia. *J Neural Transm (Vienna).* 2021 Apr;128(4):531-537.

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCNEU029**

**NEUROMUSCULAR DRUGS
BOTULINUM TOXIN**
See [Appendix A](#) for medications covered by policy

19. Bastian RW, Smithson ML. Inability to Belch and Associated Symptoms Due to Retrograde Cricopharyngeus Dysfunction: Diagnosis and Treatment. OTO Open. 2019 Mar 15;3(1):2473974X19834553.
20. Jönsson CH, Plaschke CC. Retrograde cricopharyngeal dysfunction and treatment with botulinum toxin: a systematic review. Eur Arch Otorhinolaryngol. 2024 Apr 2.

APPENDIX A.

| Brand Name | Generic Name |
|-------------------|--------------------------|
| Botox® | onabotulinumtoxinA |
| Daxxify® | daxibotulinumtoxinA-lanm |
| Dysport® | abobotulinumtoxinA |
| Jeuveau® | prabotulinumtoxinA-xvfs |
| Myobloc® | rimabotulinumtoxinB |
| Xeomin® | incobotulinumtoxinA |