



Drug Coverage Policy

Effective Date..... 5/15/2026

Coverage Policy Number IP0637

Policy Title..... Botox

Botulinum Toxins – Botox

- Botox® (onabotulinumtoxinA injection – Allergan/AbbVie)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Botox (onabotulinumtoxinA), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following uses:¹

- **Blepharospasm** associated with dystonia, including benign essential blepharospasm or seventh (VII) nerve disorders in patients ≥ 12 years of age.

- **Cervical dystonia**, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.
- **Hyperhidrosis, severe primary axillary** which is inadequately managed with topical agents in adults.
- **Migraine headache prophylaxis (prevention)**, in adults with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).
- **Neurogenic detrusor overactivity (NDO) in pediatric patients** ≥ 5 years of age who have had an inadequate response to or are intolerant of an anticholinergic medication.
- **Overactive bladder (OAB)** with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.
- **Spasticity** in patients ≥ 2 years of age.
- **Strabismus** in patients ≥ 12 years of age.
- **Urinary incontinence due to detrusor overactivity associated with a neurological condition** (e.g., spinal cord injury, multiple sclerosis) in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.

In regard to the indication of migraine headache prophylaxis, an updated position statement for the prevention of migraines from the American Headache Society (2024) notes that specifically for prevention of chronic migraine with or without aura, Botox should be considered a first-line treatment recommendation without a requirement for prior failure of other classes of migraine preventative treatment.²

Other Uses with Supportive Evidence

Botulinum toxin type A has been used to treat a multitude of disorders characterized by abnormal muscle contraction and the benefit of these products has been demonstrated in the treatment of gastrointestinal, genitourinary, ocular, and autonomic nervous system disorders.^{3,8}

Botulinum toxins have been studied in a variety of indications outside of FDA-approved uses.¹⁸⁻²⁰ Literature is available to support use of Botox in the following conditions:

- **Achalasia:** The American College of Gastroenterology (ACG) clinical guideline for the diagnosis and management of esophageal achalasia (2020) recommends the use of botulinum toxin (formulation not specified) as first-line therapy for patients with achalasia who are unfit for definitive therapies for the treatment of achalasia such as pneumatic dilation or surgical myotomy.⁴
- **Anal Fissure:** The ACG clinical guideline for the management of benign anorectal disorders (2021) suggests that botulinum toxin A injections (formulation not specified) may be attempted for patients with chronic anal fissures in whom calcium channel blockers fail or as an alternative option to calcium channel blockers (conditional recommendation; quality of evidence low).⁵
- **Dystonia, Focal Upper Limb:** Historical guidelines for the treatment of movement disorders from the American Academy of Neurology (AAN) support use of botulinum toxins in focal limb dystonia of the upper extremity (focal hand dystonia, i.e. writer's cramp) [Level B recommendation].⁷ Botulinum toxin is considered the treatment of choice for most focal dystonias.⁶ An evidence-based review and assessment (2013) for the treatment of focal upper limb dystonia indicate Botox should be considered (Level B recommendation).²⁸

- **Essential Tremor:** According to the clinical practice parameter on essential tremor by the AAN (2011; reaffirmed 2022), propranolol and primidone are first-line therapy.¹⁴ Second-line medication options include alprazolam, atenolol, sotalol, gabapentin, and topiramate. The guidelines recommend botulinum toxin A may be considered in medically refractory cases of limb, head, and voice tremor associated with essential tremor (Level C), while an evidence-based review and assessment (2013) supports Botox as a Level B recommendation.^{14,28} A 2023 multicenter, double-blind, randomized controlled trial published in NEJM demonstrated that botulinum toxin type A injections significantly improved essential head tremor, with 31% of treated patients achieving at least a 2-point improvement on the Clinical Global Impression scale compared to 9% in the placebo group (P = 0.009).³⁴
- **Hemifacial Spasm:** Per historical AAN guidelines for the treatment of movement disorders, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C recommendation).⁷ Data with Botox and Dysport® (abobotulinumtoxinA injection) are cited in the recommendations regarding hemifacial spasm. An evidenced-based review and assessment (2013) for the treatment of hemifacial spasm indicate Botox should be considered (Level B recommendation) and Dysport may be considered (Level C recommendation).²⁸
- **Hyperhidrosis, Gustatory:** Botox is recommended as a first-line option for gustatory sweating by the International Hyperhidrosis Society.¹⁵
- **Hyperhidrosis, Primary Axillary, Palmar, Plantar, and Craniofacial:** Guidelines from the International Hyperhidrosis Society support use of Botox in patients with focal axillary, palmar, plantar, and craniofacial hyperhidrosis who have failed to respond to topical antiperspirant therapy.^{15-17,33} Also, the efficacy of Botox is well-established in the treatment of primary and focal palmar hyperhidrosis based on data from both randomized, double-blind, placebo-controlled studies and open-label studies.^{19,21}
- **Laryngeal Dystonia (Spasmodic Dysphonia):** Botulinum toxin A is the most widely accepted treatment for spasmodic dysphonia, a focal laryngeal dystonia, and is viewed as the treatment of choice by the American Academy of Otolaryngology-Head and Neck Surgery (2018).⁹ Per the guideline, clinicians should offer, or refer to a clinician who can offer, botulinum toxin injections for treatment of dysphonia caused by spasmodic dysphonia and other types of laryngeal dystonia. Historical AAN guidelines for the treatment of movement disorders note that botulinum toxin is probably effective and should be considered for adductor type laryngeal dystonia (spasmodic dysphonia) [Level B recommendation].⁷ An evidence-based review and assessment (2013) for the treatment of adductor laryngeal dystonia indicate Botox may be considered (Level C recommendation).²⁸
- **Oromandibular Dystonia:** Small clinical trials have shown botulinum toxin A to be effective in treating oromandibular dystonia.^{11,12} The American Academy of Oral Medicine clinical practice statement on oromandibular dystonia recommend the use of botulinum type A injections (Botox is mentioned).¹⁰ A five year trial with Dysport for the treatment of focal movement disorders including oromandibular dystonia showed effectiveness and no new safety concerns.¹³ An evidence-based review and assessment (2013) for the treatment of oromandibular dystonia indicate Botox and Dysport may be considered (level C recommendation).²⁸ Of note, Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.²⁷

- **Sialorrhea:** Botulinum toxin A has been studied in the treatment of sialorrhea associated with Parkinson's Disease, parkinsonian syndromes, cerebral palsy, head and neck carcinoma, neurodegenerative disease, stroke, and amyotrophic lateral sclerosis.¹⁸ A review of the literature on medical treatment of sialorrhea found that Botox is probably effective for the treatment of this condition (Level B evidence).²⁴

Dosing Information

The general approach for first time botulinum toxin injections is to focus on using minimum effective starting doses and titrate based on patient response for further treatments.²⁷ Toxin distribution varies between the commercially available botulinum toxin products.¹ Labeling for the botulinum toxin products states there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity. Studies have attempted to establish a conversion ratio between botulinum toxin products with variable results; however, conversion ratios of 1:1 for Botox to Xeomin, 1:2-3 for Botox to Dysport have been suggested.¹⁸

Botox is not recommended to be injected more frequently than once every 3 months, and botulinum toxins appear to have an approximately 3-month duration of effect or longer, depending on the site of injection.¹ The Botox prescribing information advises that in a 3-month interval, an adult should not exceed a total dose of 400 units and a pediatric patient should not exceed a total dose of the lesser of 10 units/kg or 340 units.

Definitive dosing has not been established for off-label uses of botulinum toxins, including Botox. Specific considerations by indication are noted below:

- **Achalasia:** Botox has been studied for achalasia in several trials; doses higher than 100 units per treatment have not been shown to be more effective.⁴
- **Anal Fissures:** The ACG guidelines (2021) suggest botulinum toxin A injections (formulation not specified) may be used at doses of 5-100 units in patients with refractory, chronic anal fissures.⁵
- **Essential Tremor:** Published clinical trial data and consensus among movement disorder specialists suggest doses between 75 to 100 units are effective.³⁴
- **Hemifacial Spasm:** While no standardized dose has been established, a retrospective review of 470 botulinum toxin type A injection sessions administered to 68 patients over 16 years reported doses of up to 100 units, with an average dose of 34.5 units per session.³⁵
- **Hyperhidrosis, Gustatory and Primary Craniofacial:** Botox is administered as intradermal injections spaced 0.5 – 1 cm apart in a grid pattern over the affected facial area. Typical dosages utilized are 1-5 units per cm².³⁶⁻²⁹
- **Laryngeal (Spasmodic) Dystonia:** No recommended dose for this off label indication has been established; however, compendia recommend an upper limit of 25 units which is supported by several clinical trials utilizing multiple dosing regimens without exceeding 25 units.²⁹⁻³²
- **OAB:** The American Urological Association (AUA) guideline on [non-neurogenic] OAB (2024) indicate patients with inadequate response and minimal side effects to Botox 100 units may be offered 200 units.²⁵
- **Sialorrhea:** Xeomin® (incobotulinumtoxinA injection) is indicated for this use.²² Per Xeomin labeling, the maximum recommended dose for adults is 100 units (50 units per side) and for pediatric patients is 75 units (37.5 units per side), administered not more frequently than once every 16 weeks. Recommendations for maximum dosing and

frequency for Botox are based on suggested relative conversion of 1:1 for Botox to Xeomin.²³

Coverage Policy

Policy Statement

Prior Authorization is required for benefit coverage of Botox. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Botox as well as the monitoring required for adverse events and long-term efficacy, approval for a diagnosis of migraine headache prevention requires Botox to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Benefit coverage is not recommended for Botox Cosmetic or cosmetic use.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Botox is considered medically necessary when ONE of the following criteria are met:

FDA-Approved Indications

- 1. Blepharospasm.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.
 - A)** Patient is \geq 12 years of age; AND
 - B)** Patient has intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle **[documentation required]**; AND
 - C)** Prescribed by or in consultation with a neurologist or ophthalmologist

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 3 months.
- 2. Cervical Dystonia.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
Note: Cervical dystonia is also referred to as spasmodic torticollis.
 - A)** Patient is \geq 18 years of age; AND
 - B)** Patient has a diagnosis of cervical dystonia **[documentation required]**; AND
 - C)** Patient has sustained head torsion and/ or tilt with limited range of motion in the neck **[documentation required]**; AND
 - D)** Prescribed by or in consultation with a pain medicine specialist, neurologist, or physical medicine and rehabilitation physician

Dosing. Approve up to a maximum dose of 300 units, administered not more frequently than once every 3 months.

3. Hyperhidrosis, Primary Axillary. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient is ≥ 18 years of age; AND
- B)** Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; AND
- C)** The prescriber has excluded secondary causes of hyperhidrosis; AND
- D)** Patient has tried at least one topical prescription agent for axillary hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance.
Note: Examples of prescription topical agents for the treatment of axillary hyperhidrosis include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution), Qbrexza (glycopyrronium cloth 2.4% for topical use), Sofdra (glycopyrronium 12.45% topical gel).

Dosing. Approve up to a maximum dose of 50 units per axilla, administered not more frequently than once every 3 months.

4. Chronic Migraine Headache Prevention. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient is ≥ 18 years of age; AND
- B)** Patient has ≥ 15 headache days per month with a headache lasting 4 hours per day or longer (prior to initiating a migraine-preventative medication); AND
- C)** Botox is being prescribed by or in consultation with a neurologist or headache specialist; AND
- D)** If the patient is currently taking Botox for chronic migraine headache prevention, the patient has had a significant clinical benefit from the medication as determined by the prescriber [**documentation required**].
Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Botox was initiated.

Dosing. Approve up to a maximum dose of 155 units, administered not more frequently than once every 12 weeks.

5. Neurogenic Detrusor Overactivity (NDO), Pediatric. Approve for 1 year if the patient meets BOTH of the following (A and B):

- A)** Patient is ≥ 5 years of age; AND
- B)** Patient has tried at least one other pharmacologic therapy for the treatment of neurogenic detrusor overactivity (NDO).
Note: Examples of other NDO pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult urinary incontinence due to detrusor overactivity associated with a neurological condition, refer to the FDA-Approved Indication below.

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

6. Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency (Adult). Approve for 1 year if the patient meets BOTH of the following (A and B):

- A)** Patient is ≥ 18 years of age; AND
- B)** Patient has tried at least one other pharmacologic therapy for the treatment of overactive bladder (OAB).

Note: Examples of other OAB pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult urinary incontinence due to detrusor overactivity associated with a neurological condition, refer to the FDA-Approved Indication below.

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

7. Spasticity, Limb(s). Approve for 1 year if the patient is ≥ 2 years of age.

Dosing. Approve ONE of the following regimens (A, B or C):

A) Lower limb spasticity: Approve ONE of the following regimens (i or ii):

- i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
- ii. Patient is < 18 years of age: Approve up to a maximum dose of 8 units/kg (not to exceed 300 units), administered not more frequently than once every 12 weeks.

B) Upper limb spasticity: Approve ONE of the following regimens (i or ii):

- i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
- ii. Patient is < 18 years of age: Approve up to a maximum dose of 6 units/kg (not to exceed 200 units), administered not more frequently than once every 12 weeks.

C) If treating BOTH upper AND lower limb spasticity: Approve ONE of the following regimens (i or ii):

- i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
- ii. Patient is < 18 years of age: Approve up to a maximum dose of 10 units/kg (not to exceed 340 units), administered not more frequently than once every 12 weeks.

8. Strabismus. Approve for 1 year if the patient is ≥ 12 years of age.

Note: Common types of strabismus include esotropia, exotropia, hypertropia, hypotropia.

Dosing. Approve up to a maximum dose of 25 units in any one muscle, administered not more frequently than once every 3 months.

9. Urinary Incontinence Due to Detrusor Overactivity Associated with a Neurological Condition (Adult). Approve for 1 year if the patient meets BOTH of the following (A and B):

Note: Examples of neurological conditions associated with urinary incontinence include spinal cord injury, multiple sclerosis, spina bifida.

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least one other pharmacologic therapy for the treatment of urinary incontinence.

Note: Examples of other pharmacologic therapies for urinary incontinence include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, refer to the FDA-Approved Indication above. For treatment of pediatric neurogenic detrusor overactivity (NDO), refer to the FDA-Approved Indication above.

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

10. Achalasia. Approve for 1 year if the patient is ≥ 18 years of age.

Note: Achalasia is also referred to as esophageal achalasia or achalasia cardia.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

11. Anal Fissure, Chronic. Approve for 1 year if the patient is ≥ 18 years of age.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

12. Dystonia, Focal Upper Limb. Approve for 1 year if the patient is ≥ 18 years of age. Note: An example of focal upper limb dystonia is focal hand dystonia.

Dosing. Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

13. Essential Tremor. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least one other pharmacologic therapy for the treatment of tremors.

Note: Examples of pharmacologic therapies for essential tremor include primidone, propranolol, atenolol, sotalol, alprazolam, gabapentin, topiramate.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

14. Hemifacial Spasm. Approve for 1 year if the patient is ≥ 18 years of age.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

15. Hyperhidrosis, Gustatory. Approve for 1 year if the patient is ≥ 18 years of age.

Note: Gustatory hyperhidrosis is also referred to as Frey's Syndrome.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

16. Hyperhidrosis, Primary Palmar/Plantar/Craniofacial. Approve for 1 year if the patient meets ALL of the following (A, B, C and D):

A) Patient is ≥ 18 years of age; AND

B) Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; AND

C) The prescriber has excluded secondary causes of hyperhidrosis; AND

D) Patient has tried at least one topical agent for the treatment of hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance.

Note: Examples of topical agents for the treatment of hyperhidrosis include topical aluminum chloride antiperspirants.

Dosing. Approve ONE of the following regimens (A or B):

A) Hyperhidrosis, Primary Craniofacial: Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months; OR

B) Hyperhidrosis, Primary Palmar/Plantar: Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

17. Laryngeal Dystonia (Spasmodic Dysphonia). Approve for 1 year if the patient is \geq 18 years of age.

Dosing. Approve up to a maximum dose of 25 units, administered not more frequently than once every 3 months.

18. Oromandibular Dystonia. Approve for 1 year if the patient is \geq 18 years of age.

Note: Oromandibular dystonia is also referred to as orofacial dystonia.

Dosing. Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

19. Sialorrhea, Chronic. Approve for 1 year if the patient is \geq 18 years of age.

Dosing. Approve up to a maximum dose of 100 units (50 units per side), administered not more frequently than once every 16 weeks.

Conditions Not Covered

Botox (onabotulinumtoxinA) for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

1. Cosmetic Use. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.

Note: Examples of cosmetic uses include facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, or rejuvenation of the periorbital region.

2. Gastroparesis. The ACG issued clinical guidelines on the management of gastroparesis (2013).²⁶ ACG does not recommend the use of botulinum toxin injected into the pylorus as a treatment for gastroparesis. This is based on two double-blind, placebo-controlled studies which did show some improvement in gastric emptying, but no improvement in symptoms compared with placebo.

Coding Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Blepharospasm

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|-------------|---|
| 64612 | Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm) |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Cervical Dystonia

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 64616 | Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis) |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Hyperhidrosis, Primary Axillary

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 64650 | Chemodenervation of eccrine glands; both axillae |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Migraine Headache Prevention

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 64615 | Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal, and accessory nerves, bilateral (eg, for chronic migraine) |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Neurogenic Detrusor Overactivity (NDO), Pediatric

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 52287 | Cystourethroscopy, with injection(s) for chemodenervation of the bladder |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency (Adult)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 52287 | Cystourethroscopy, with injection(s) for chemodenervation of the bladder |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Spasticity, Limb(s)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 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 |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Strabismus

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 67345 | Chemodenervation of extraocular muscle |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Urinary Incontinence Due to Detrusor Overactivity Associated with a Neurological Condition (Adult)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 52287 | Cystourethroscopy, with injection(s) for chemodenervation of the bladder |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Achalasia

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 43201 | Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance |
| 43236 | Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Anal Fissure, Chronic

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 46505 | Chemodenervation of internal anal sphincter |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Dystonia, Focal Upper Limb

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 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) |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Essential Tremor

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | 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) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral |
| 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 |
| 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) |

| HCPCS Codes | Description |
|--------------------|--|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |
| S2340 | Chemodenervation of abductor muscle(s) of vocal cord |
| S2341 | Chemodenervation of adductor muscle(s) of vocal cord |

Hemifacial Spasm

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 64612 | Chemodenerivation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm) |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Hyperhidrosis, Gustatory

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 64653 | Chemodenerivation of eccrine glands; other area(s) (eg, scalp, face, neck), per day |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Hyperhidrosis, Primary Palmar/Plantar/Facial

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 64653 | Chemodenerivation of eccrine glands; other area(s) (eg, scalp, face, neck), per day |
| 64999 [†] | Unlisted procedure, nervous system |

[†]Note: Covered when used to report chemodenerivation of the hands for palmar/plantar hyperhidrosis.

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Laryngeal Dystonia (Spasmodic Dysphonia)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | 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) (eg, chemodenevation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral |
| 64617 | Chemodenevation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed |

| HCPCS Codes | Description |
|--------------------|---|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |
| S2340 | Chemodenevation of abductor muscle(s) of vocal cord |
| S2341 | Chemodenevation of adductor muscle(s) of vocal cord |

Oromandibular Dystonia

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|--|
| 64612 | Chemodenevation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm) |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

Sialorrhea, Chronic

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|--------------------|---|
| 64611 | Chemodenevation of parotid and submandibular salivary glands, bilateral |

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| J0585 | Injection, onabotulinumtoxinA, 1 unit |

***Current Procedural Terminology (CPT®) © 2024 American Medical Association: Chicago, IL.**

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Revision Details

| Type of Revision | Summary of Changes | Date |
|------------------|---|-----------|
| New | New policy. | 7/15/2025 |
| Annual Revision | <p>Updated policy template.</p> <p>Chronic Migraine Headache Prevention: The qualifier "chronic" was added to the condition of approval. The qualifier "migraine" was removed from "Patient has ≥ 15 headache days per month with a headache lasting 4 hours per day or longer." Also, the requirement "prior to initiation of Botox therapy" was clarified to "prior to initiating a migraine-preventative medication."</p> <p>Essential Tremor: The dosing limitation was decreased from 400 units to 100 units.</p> <p>Hemifacial Spasm: The dosing limitation was decreased from 400 units to 100 units.</p> <p>Hyperhidrosis, Gustatory: The dosing limitation was decreased from 400 to 100 units.</p> <p>Hyperhidrosis, Primary Craniofacial: The qualifier "facial" was replaced with "craniofacial.". The dosing limitation was decreased from 400 to 100 units.</p> | 5/15/2026 |

The policy effective date is in force until updated or retired.

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