



Drug Coverage Policy

Effective Date..... 7/15/2025

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 in the treatment of essential tremor.¹⁴ Second-line medication options include alprazolam, atenolol, sotalol, gabapentin (as monotherapy), and topiramate. The guidelines recommend that botulinum toxin A may be considered in medically refractory cases of limb, head, and voice tremor associated with essential tremor (Level C recommendation for

limb, head, and voice tremor). An evidence-based review and assessment (2013) for the treatment of tremor indicate Botox should be considered (Level B recommendation).²⁸

- **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® (onabotulinumtoxinA injection) 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 Palmar, Plantar, and Facial:** Guidelines from the International Hyperhidrosis Society support use of Botox in patients with focal palmar, plantar, and craniofacial hyperhidrosis who have failed to respond to topical antiperspirant therapy.¹⁵⁻¹⁷ 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

Definitive dosing has not been established for off-label uses of botulinum toxins, including Botox. In general, 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, adults should not exceed a total dose of 400 units. Pediatric patients should not exceed a total dose of the lesser of 10 units/kg or 340 units in a 3-month interval. 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
- **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 recommended for prescription benefit coverage of Botox. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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 requires Botox to be prescribed by a physician who has consulted with or who specializes in the condition.

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.

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 ≥ 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 ≥ 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. 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 migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy); 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 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, 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 400 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 400 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 400 units, administered not more frequently than once every 3 months.

16. Hyperhidrosis, Primary Palmar/Plantar/Facial. 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 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 ≥ 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 ≥ 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 ≥ 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

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 Uses.** 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	Chemodenervation 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	Chemodenervation 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	Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day
64999 [†]	Unlisted procedure, nervous system

[†]Note: Covered when used to report chemodenervation of the hands for palmar 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, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral
64617	Chemodenervation 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	Chemodenervation of abductor muscle(s) of vocal cord
S2341	Chemodenervation 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	Chemodenervation 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	Chemodenervation 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.**

References

1. Botox® injection [prescribing information]. Madison, NJ: Allergan; November 2023.

2. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; 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. *Headache*. 2024;64(4):333-341.
3. Brin MF, Blitzer A. The pluripotential evolution and journey of Botox (onabotulinumtoxinA). *Medicine (Baltimore)*. 2023;102(S1): e32373.
4. Vaezi MF, Pandolfino JE, Yadlapati RH, et al. ACG Clinical Guidelines: diagnosis and management of achalasia. *Am J Gastroenterol*. 2020;115(9):1393-1411.
5. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: management of benign anorectal disorders. *Am J Gastroenterol*. 2021;116(10):1987-2008.
6. Adam OR, Jankovic J. Treatment of dystonia. *Parkinsonism Relat Disord*. 2007;13 Suppl 3: S362-S368. doi:10.1016/S1353-8020(08)70031-2
7. Simpson DM, Blitzer A, Brashear A, et al. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008; 70:1699-1706.
8. Simpson DM, Hallett M, Ashman EJ, et al. Practice guidelines update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016; 86:1818-1826.
9. Stachler RJ, Francis DO, Schwartz SR, et al. Clinical practice guideline: hoarseness (dysphonia). *Otolaryngology – Head and Neck Surgery*. 2018; Supplement:1-42.
10. France K, Stoopler ET. The American Academy of Oral Medicine Clinical Practice Statement: Oromandibular dystonia. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2018;125(4):283-285.
11. Müller J, Wenning GK, Wissel J, Seppi K, Poewe W. Botulinum toxin treatment in atypical parkinsonian disorders associated with disabling focal dystonia. *J Neurol*. 2002;249(3):300-304.
12. Jankovic J, Orman J. Botulinum A toxin for cranial-cervical dystonia: a double-blind, placebo-controlled study. *Neurology*. 1987;37(4):616-623.
13. Van den Bergh P, Francart J, Mourin S, Kollmann P, Laterre EC. Five-year experience in the treatment of focal movement disorders with low-dose Dysport botulinum toxin. *Muscle Nerve*. 1995;18(7):720-729.
14. Zesiewicz TA, Elble R, Louis ED, et al. Evidence-based guideline update: treatment of essential tremor: report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2011; 77:1752-1755.
15. International Hyperhidrosis Society. Primary focal craniofacial and gustatory hyperhidrosis (Frey's Syndrome). Updated January 15, 2012. Available at: <https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-facial-and-gustatory.html>. Accessed on August 19, 2024.
16. International Hyperhidrosis Society. Primary focal palmar hyperhidrosis. Updated January 15, 2012. Available at: <https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-palmar.html>. Accessed on August 19, 2024.
17. International Hyperhidrosis Society. Primary focal plantar hyperhidrosis. Updated January 15, 2012. Available at: <https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-plantar.html>. Accessed on August 19, 2024.
18. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. *J Neurol Sci*. 2005;235(1-2):1-9.
19. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 1. *Am J Health Syst Pharm*. 2006;63(2): 145-152.
20. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 2. *Am J Health Syst Pharm*. 2006;63(3):225-232.
21. Lowe N, Campanati A, Bodokh I, et al. The place of botulinum toxin type A in the treatment of focal hyperhidrosis. *Br J Dermatol*. 2004;151(6):1115-1122.
22. Xeomin® injection [prescribing information]. Raleigh, NC: Merz; August 2021.

23. Scaglione F. Conversion ratio between Botox®, Dysport®, and Xeomin® in clinical practice. *Toxins (Basel)*. 2016;8(3):65.
24. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: anatomy, pathophysiology, and treatment with emphasis on the role of botulinum toxin. *Toxins*. 2013; 5:1010-1031.
25. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. *J Urol*. 2024;212(1):11-20.
26. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: management of gastroparesis. *Am J Gastroenterol*. 2013;108(1):18-38.
27. Hassell TJW, Charles D. Treatment of Blepharospasm and Oromandibular Dystonia with Botulinum Toxins. *Toxins (Basel)*. 2020;12(4):269. Published 2020 Apr 22.
28. Hallett M, Albanese A, Dressler D, Segal KR, Simpson DM, Truong D, Jankovic J. Evidence-based review, and assessment of botulinum neurotoxin for the treatment of movement disorders. *Toxicon*. 2013 Jun 1; 67:94-114.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	7/15/2025

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

“Cigna Companies” refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.