

Clinical Criteria

| | | | |
|--------------------|-----------------|--------------------------|--------------------------------------|
| Subject: | Botulinum Toxin | Publish Date: | 06/15/202001/25/2021 |
| Document #: | ING-CC-0032 | Last Review Date: | 05/15/202012/14/2020 |
| Status: | Revised | | |

Table of Contents

| | | |
|-----------------------------------|----------------------------------|----------------------------|
| Overview | Coding | References |
| Clinical criteria | Document history | |

Overview

This document addresses the use of botulinum toxin agents: Dysport (abobotulinumA), Xeomin (incobotulinumtoxin A), Botox (onabotulinumtoxin A), and Myobloc (rimabotulinumtoxin B).

Botulinum is a family of toxins produced by the anaerobic organism Clostridia botulinum. There are seven distinct serotypes designated as type A, B, C-1, D, E, F, and G. In this country, four preparations of botulinum are available, produced by two different strains of bacteria: type A (Botox [onabotulinumtoxinA], Dysport [abobotulinumtoxinA], and Xeomin [incobotulinumtoxinA]) and type B (Myobloc [rimabotulinumtoxinB]). When administered intramuscularly, all botulinum toxins reduce muscle tone by interfering with the release of acetylcholine from nerve endings. However, it should be noted that these drugs are not interchangeable and the potency ratios for dosing cannot be converted. Careful adherence to the specific instructions for dosing in the package insert is recommended.

The U.S. Food and Drug Administration (FDA) approved label for Botox states that it is indicated for the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain; primary axillary hyperhidrosis that is inadequately managed with topical agents; strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or facial nerve (VII nerve) disorders in individuals older than 12 years; urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have an inadequate response to or are intolerant of an anticholinergic medication; overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or are intolerant of an anticholinergic medication; prophylaxis of chronic migraine headaches in adults; upper limb spasticity; lower limb spasticity; and several cosmetic indications including the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity, moderate to severe lateral canthal lines (associated with orbicularis oculi activity) and moderate to severe forehead lines (associated with frontalis muscle activity) in adults less than or equal to 65 years of age.

The FDA approved label for Myobloc states it is indicated for the treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain and chronic sialorrhea.

The FDA approved label for Dysport specifies that it is indicated for the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain, upper limb spasticity in adults and in pediatric patients 2 years of age and older excluding spasticity caused by cerebral palsy, lower limb spasticity in pediatric patients 2 years of age and older, and the temporary improvement in the appearance of moderate to severe glabellar lines in adults younger than 65 years of age.

Xeomin has received FDA approval for the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain, abnormal spasm of the eyelids blepharospasm in adults, adults with upper limb spasticity, children with upper limb spasticity excluding spasticity caused by cerebral palsy, excessive salivation (chronic sialorrhea), and the temporary improvement in the appearance of moderate to severe frown lines between the eyebrows (glabellar lines) in adults.

Dystonia is a general term describing a state of abnormal or disordered tonicity of muscle. As an example, achalasia is a dystonia of the lower esophageal sphincter, while cervical dystonia is also known as torticollis. Spasticity is a subset of dystonia, describing a velocity-dependent increase in tonic-stretch reflexes with exaggerated tendon jerks. Spasticity typically is associated with injuries to the central nervous system. Spasticity is a common feature of cerebral palsy. Since its FDA approval in 1991, Botox has been used for a wide variety of off-label indications; all associated with dystonia, ranging from achalasia, spasticity after strokes, cerebral palsy, and anal fissures. In addition to widening indications, Botox has also been used in children under 12, particularly for the treatment of cerebral palsy and is now FDA approved to treat various conditions in the pediatric population.

Botulinum toxin has been utilized for many other conditions including anismus (pelvic floor dyssynergia), Behcet's syndrome, benign prostatic hyperplasia, brachial plexus palsy, carpal tunnel, myofascial pain syndrome, Raynaud's syndrome, atypical facial pain (also known as persistent idiopathic facial pain [PIFP]), low back pain, Tourette's syndrome and Parkinson's disease. There is limited evidence for efficacy of botulinum toxin in these conditions.

BoNT agents have black box warnings regarding the potential for distant spread of toxin effect. This can produce symptoms including asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk is likely greatest in children treated for spasticity but can also occur in adults.

Dysport contains lactose as an inactive ingredient. Individuals with a severe milk protein allergy should avoid use due to the risk of anaphylactic reactions.

Botulinum toxin agents are not interchangeable and dosing units of one agent cannot be converted or compared to dosing units of another botulinum toxin agent.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Botulinum Toxin

Requests for botulinum toxin may be approved if the following criteria are met:

- I. Individual has one of the following diagnoses:
 - A. Disorders listed below if associated with spasticity or dystonia:
 1. Blepharospasm; **OR**
 2. Cerebral palsy; **OR**
 3. Facial nerve (VII) dystonia; **OR**
 4. Hemifacial spasm; **OR**
 5. Hereditary spastic paraparesis; **OR**
 6. Idiopathic torsion dystonia; **OR**
 7. Lower limb spasticity; **OR**
 8. Multiple sclerosis; **OR**
 9. Neuromyelitis optica; **OR**
 10. Organic writer's cramp; **OR**
 11. Orofacial/oromandibular dystonias including jaw closure dystonia and Meige's syndrome; **OR**
 12. Schilder's disease; **OR**
 13. Spasmodic dysphonia or laryngeal dystonia (a disorder of speech due to abnormal control of the laryngeal muscles present only during the specific task of speaking); **OR**
 14. Spastic hemiplegia; **OR**
 15. Spasticity related to stroke, spinal cord injury, or traumatic brain injury; **OR**
 16. Dystonia-associated strabismus; **OR**
 17. Symptomatic torsion dystonia; **OR**
 18. Other forms of upper motor neuron spasticity; **OR**
 19. Upper limb spasticity; **OR**
 - B. Achalasia; **OR**
 - C. Anal fissures; **OR**
 - D. Significant drooling in individuals who are unable to tolerate scopolamine; **OR**
 - E. Idiopathic overactive bladder in adults who are unresponsive or intolerant of a trial of anticholinergic therapy; **OR**
 - F. Neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy; **OR**
 - G. Hirschsprung disease and associated functional obstruction caused by the inability of the internal anal sphincter to relax after prior surgical treatment; **OR**

OR

- II. Individual has a diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; **AND**
- III. Individual is requesting initial treatment; **AND**

- IV. Individual has a history of recurrent clonic or tonic involuntary contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius or posterior cervical muscles; **AND**
- V. Abnormal posturing, with limited range of motion in the neck, or sustained head tilt; **AND**
- VI. The duration of the condition is greater than 6 months;

- OR**
- VII. Individual has a diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; **AND**
 - VIII. Individual is requesting subsequent injections; **AND**
 - IX. Response to initial treatment documented in medical records;

- OR**
- X. Individual has a diagnosis of chronic migraine headaches; **AND**
 - XI. Individual is requesting initial treatment; **AND**
 - XII. Individual has 15 (fifteen) or more headache-days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3); **AND**
 - XIII. Individual has had a trial of and inadequate response or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence; ICSI 2013, high quality evidence):
 - A. One of the following antidepressants: amitriptyline, venlafaxine; **OR**
 - B. One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol; **OR**
 - C. The following calcium channel blocker: verapamil; **OR**
 - D. One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin; **AND**
 - XIV. Individual will not use concomitantly with injectable calcitonin gene-related peptide (CGRP) agents for migraine prophylaxis;

Initial approval duration for chronic migraine headaches: 6 months

- OR**
- XV. Individual has a diagnosis of chronic migraine headaches; **AND**
 - XVI. Individual is requesting continued treatment; **AND**
 - XVII. Individual has completed an initial 6-month trial the following criteria are met:
 - A. Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month; **AND**
 - B. Individual has obtained clinical benefit deemed significant by individual or prescriber; **AND**
- ~~B.XVIII. Individual will not use concomitantly with injectable calcitonin gene-related peptide (CGRP) agents for migraine prophylaxis.~~

Renewal approval duration for chronic migraine headaches: 1 year

- OR**
- ~~XVIII.XIX.~~ Individual has a diagnosis of primary hyperhidrosis; **AND**
 - ~~XIX.XX.~~ Individual has failed a 6 month trial of any one or more types of non-surgical treatment (for example, topical dermatologics such as aluminum chloride, tannic acid, glutaraldehyde or anticholinergics, systemic anticholinergics, tranquilizers or non-steroid anti-inflammatory drugs); **AND**
 - ~~XX.XXI.~~ Individual has one of the following:
 - A. Presence of medical complications or skin maceration with secondary infection; **OR**
 - B. Significant functional impairment, as documented in the medical record;

- OR**
- ~~XXI.XXII.~~ Individual has a diagnosis of secondary hyperhidrosis; **AND**
 - ~~XXII.XXIII.~~ Condition is related to surgical complications; **AND**
 - ~~XXIII.XXIV.~~ Individual has presence of medical complications or skin maceration with secondary infection; **AND**
 - ~~XXIV.XXV.~~ Individual has significant functional impairment, as documented in the medical record.

Requests for botulinum toxin may not be approved for the following:

- I. Individual is using for skin wrinkles or other cosmetic indications; **OR**
- II. Individual has headache diagnosis other than chronic migraine (example, tension, episodic migraine [14 migraine days per month or less], or chronic daily headaches); **OR**
- III. Individual has had a treatment failure of botulinum toxin for any condition listed above (exception would be due to product specific intolerance or allergic reaction); **OR**
- IV. Individual has any diagnosis not listed as an approvable diagnosis, including, but not limited to, the following:
 - A. Anismus (pelvic floor dyssynergia); **OR**
 - B. Behcet's syndrome; **OR**
 - C. Benign prostatic hyperplasia; **OR**
 - D. Brachial plexus palsy; **OR**
 - E. Carpal tunnel syndrome; **OR**
 - F. Chronic motor tic disorder; **OR**
 - G. Disorders of the esophagus (except as listed above in the approvable section) ; **OR**
 - H. Epicondylitis; **OR**
 - I. Fibromyalgia/fibromyositis; **OR**

Formatted: Font: Bold

Formatted: Left, Indent: Hanging: 0.65", Tab stops: 0.44", Left + Not at 1.15"

Formatted: Font: Not Bold

- J. Gastroparesis; **OR**
- K. Low back pain; **OR**
- L. Myofascial pain syndrome; **OR**
- M. Neck pain not related to conditions mentioned above; **OR**
- N. Nystagmus; **OR**
- O. Parkinson's disease; **OR**
- P. Post-mastectomy reconstruction syndrome; **OR**
- Q. Reynaud's syndrome; **OR**
- R. Sphincter of Oddi dysfunction; **OR**
- S. Stuttering; **OR**
- T. Tics associated with Tourette's Syndrome; **OR**
- U. Tinnitus; **OR**
- V. Tourette's Syndrome; **OR**
- W. Tremors; **OR**
- X. Urinary and anal sphincter dysfunction (except as listed above in the approvable section) ; **OR**
- Y. Vaginismus; **OR**
- Z. Whiplash-related disorders; **OR**
- AA. Zygomatic fractures.

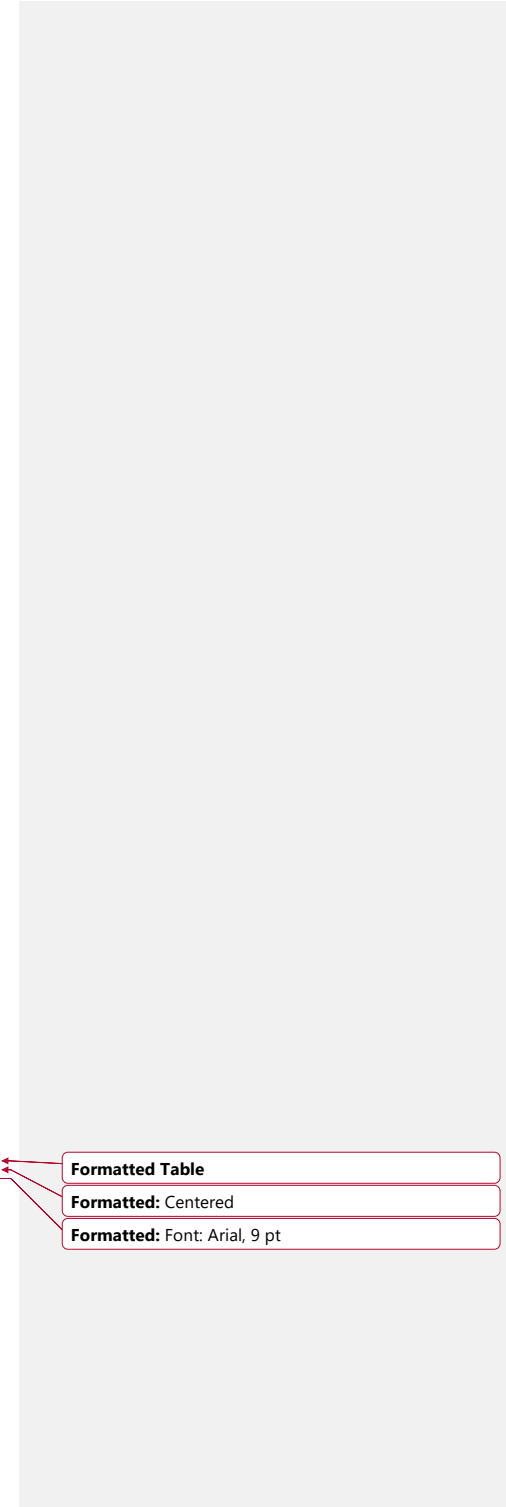
Step Therapy

FDA-approved Indications or Indications Meeting off-label drug use criteria

| | Dysport (AbobotulinumA) | Xeomin (Incobotulinumtoxin A) | Botox (Onabotulinumtoxin A) | Myobloc (Rimabotulinumtoxin B) |
|---|----------------------------|----------------------------------|---|-----------------------------------|
| Achalasia | | | Y (AHFS) | |
| Blepharospasm in adults | Y (B, IIa) | X | X | Y (AHFS) |
| Blepharospasm in children | | Y (AHFS)*** | X | Y (AHFS) |
| Cervical dystonia | X | X | X | X |
| Chronic anal fissure | | | Y (AHFS) | |
| Excessive salivation (chronic sialorrhea) | | X | Y (B, IIa)** | X |
| Hemifacial spasm | | | Y (B, IIa; AHFS) | Y (AHFS) |
| Hyperhidrosis | | | X - Primary Axillary Y - Palmer (AHFS) | Y (AHFS) |
| Incontinence- Spinal cord injury | | | X | |
| Lower limb spasticity in children 2 years of age and older | X | | X* | |
| Lower limb spasticity in adults | X | | X | |
| Meige's syndrome (idiopathic blepharospasm with facial and oromandibular dystonias) | | | Y (AHFS) | |
| Migraine prophylaxis | | | X | |
| Oromandibular dystonias | | | Y (AHFS) | |
| Overactive bladder | | | X | |
| Spasmodic dysphonia | | | Y (AHFS) | |
| Spasticity related to cerebral palsy | | | Y (B, IIb), AHFS | |
| Strabismus for 12 years of age and older | | | X | |
| Upper limb spasticity in children 2 years of age and older | X* | X* | X | |
| Upper limb spasticity in adults | X | X | X | |

X = FDA-approved Indications (excluding cosmetic indications)
 Y = Indications Meeting off-label drug use criteria
 *Excluding spasticity caused by cerebral palsy
 **Excessive salivation in advanced Parkinson's disease
 ***In patients previously treated with onabotulinumtoxinA A (Botox)

Note: When a botulinum toxin is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria



Formatted Table

Formatted: Centered

Formatted: Font: Arial, 9 pt

requiring the use of a preferred¹ agent or agents.

A benefit plan may select any one or more of the following as preferred botulinum toxin: onabotulinumtoxinA (Botox), abobotulinumA (Dysport), rimabotulinumtoxinB (Myobloc), incobotulinumtoxinA (Xeomin).

Non-Preferred Botulinum Toxin Step Therapy

Currently step therapy does not apply under the medical benefit.

Requests for a non-preferred botulinum toxin may be approved when the following criteria are met:

- I. Individual has had a trial and inadequate response or intolerance to one preferred botulinum toxin agent;
- OR**
- II. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label use policy for the prescribed indication and the requested non-preferred agent does;
- OR**
- III. If Dysport (abobotulinumtoxinA) is designated as the sole preferred agent and the individual has a known hypersensitivity to cow's milk protein.

¹Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Botulinum Toxin Quantity Limits*

| Drug | Limit Per Indication | Maximum amount allowed for indication* |
|---|--|--|
| Botox (onabotulinumtoxinA) 100 unit, 200 unit vial NOTE: follow indication-specific dosage and administration recommendations; in a 3 month interval do not exceed a total dose of: <ul style="list-style-type: none"> • Adults: 400 units • Pediatrics: the lesser of 10 units/kg or 340 units | Idiopathic Overactive Bladder: 100 units as frequently as every 12 weeks | 100 units |
| | Neurogenic Overactive Bladder: 200 units as frequently as every 12 weeks | 200 units |
| | Chronic Migraine: 155 units as frequently as every 12 weeks | 200 units |
| | Cervical Dystonia: 400 units§ as frequently as every 12 weeks | 400 units |
| | Axillary hyperhidrosis: 50 units per axilla as frequently as every 12 weeks | 100 units |
| | Blepharospasm: 200 units as frequently as every 12 weeks | 200 units |
| | Dystonia-associated strabismus: 25 units per muscle; as frequently as every 12 weeks | 100 units |
| | Upper limb spasticity in adults: Dose selected based on muscles affected, severity of muscle activity, prior response to treatment and adverse event history (maximum dose 400 units) as frequently as every 12 weeks | 400 units |
| | Lower limb spasticity in adults: 300 units to 400 units divided across ankle and toe muscles as frequently as every 12 weeks | 400 units |
| | Upper limb spasticity in pediatric patients: 3 Units/kg to 6 Units/kg (maximum 200 Units) as frequently as every 12 weeks | 200 units |
| | Lower limb spasticity in pediatric patients (excluding cerebral palsy): 4 units/kg to 8 units/kg (maximum 300 units) as frequently as every 12 weeks | 300 units |
| | Achalasia: 100 units as frequently as every 12 weeks (DP) | 100 units |
| | Hemifacial spasm: 25 units as frequently as every 12 weeks (DP) | 100 units |
| | Spasmodic Dysphonia: 25 units as frequently as every 12 weeks (DP) | 100 units |
| Other indications: Up to 400 units as frequently as every 12 weeks | 400 units | |
| Dysport (abobotulinumtoxinA) 300 unit, 500 unit vial | Upper and lower limb spasticity in adults: 1500 units (cumulative for all treated muscles) as frequently as every 12 weeks | 1500 units |
| | Cervical Dystonia: 1000 units as frequently as every 12 weeks | 1000 units |
| | Other indications: Up to 1500 units as frequently as every 12 weeks | 1500 units |
| | Upper limb spasticity in pediatric patients: 8 units/kg to 16 units/kg per limb; maximum per treatment session 16 units/kg or 640 units, whichever is lower | 800 units |
| | Lower limb spasticity in pediatric patients: 10 units/kg to 15 units/kg; total dose must not exceed 15 units/kg for unilateral lower limb or 30 units/kg for bilateral injections or 1000 units, whichever is lower | 1000 units |
| | Blepharospasm: 120 units per eye as frequently as every 12 weeks (DP) | 300 units |
| Myobloc (rimabotulinumtoxinB) 2500 | Hemifacial spasm: 220 units as frequently as every 12 weeks (DP) | 300 units |
| | Cervical dystonia: 2,500 – 5,000 units divided among effected muscles | 5000 units |
| | Chronic sialorrhea in adults: 1,500 – 3,500 units (500 units – 1,500 units per parotid) | 5000 units |

| | | |
|---|---|--------------|
| unit, 5000 unit, 10000 unit vial | gland and 250 units per submandibular gland) as frequently as every 12 weeks All other Indications: 10,000 units as frequently as every 12 weeks | 10,000 units |
| Xeomin (incobotulinumtoxinA) 200 unit, 100 unit, 50 unit vial | Cervical dystonia: Initial dose of 120 units as frequently as every 12 weeks; subsequent doses should be based on past dose, response to treatment, duration of effect and adverse event history; up to 400 units as frequently as every 12 weeks | 400 units |
| | Chronic sialorrhea: 100 units as frequently as every 16 weeks | 100 units |
| | Blepharospasm: Initial dose 50 units (25 units per eye) as frequently as every 12 weeks; subsequent doses based on past dose, response to treatment, duration of effect and adverse event history; dose should not exceed 100 units per treatment session (50 units per eye) | 100 units |
| | Upper limb spasticity: 400 units as frequently as every 12 weeks | 400 units |
| | Other indications: Up to 400 units as frequently as every 12 weeks | 400 units |

*Based on maximum dose for condition and vial size available

DP = DrugPoints off label use/dosing

§ Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; mean dose in clinical study was 236 units (25th to 75th percentile range of 198 units to 300 units)

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

| | |
|-------|--|
| 31573 | Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral |
| 46505 | Chemodenervation of internal anal sphincter [for diagnosis of anal fissure] |
| 52287 | Cystourethroscopy, with injection(s) for chemodenervation of the bladder [for specified related bladder and incontinence disorders] |
| 64647 | Chemodenervation of trunk muscle(s); 6 or more muscles |
| 67345 | Chemodenervation of extraocular muscle [for diagnosis of strabismus] |
| 46505 | Chemodenervation of internal anal sphincter [for diagnosis of Hirschsprung's disease] |
| 64611 | Chemodenervation of parotid and submandibular salivary glands, bilateral [for significant drooling] |
| 64612 | Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm or hemifacial spasm) |
| 64615 | Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine) |
| 64616 | Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis) |
| 64617 | Chemodenervation of muscle(s); larynx, unilateral, percutaneous, (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed |
| 64642 | Chemodenervation of one extremity; 1-4 muscle(s) |
| 64643 | Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) |
| 64644 | Chemodenervation of one extremity; 5 or more muscles |
| 64645 | Chemodenervation of one extremity; each additional extremity, 5 or more muscles |
| 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 |

HCPCS

| | |
|-------|---|
| J0585 | Injection, onabotulinumtoxinA, 1 unit [e.g., Botox] |
| J0586 | Injection, abobotulinumtoxinA, 5 units [Dysport] |
| J0587 | Injection, rimabotulinumtoxinB, 100 units [Myobloc] |

| | |
|--------------|---|
| J0588 | Injection, incobotulinumtoxinA, 1 unit [Xeomin] |
| S2340 | Chemodenerivation of abductor muscle(s) of vocal cord |
| S2341 | Chemodenerivation of adductor muscle(s) of vocal cord |

ICD-10 Diagnosis

| | |
|------------------------|---|
| G11.4 | Hereditary spastic paraplegia |
| G24.01-G24.09 | Drug induced dystonia |
| G24.1-G24.2 | Genetic torsion dystonia, idiopathic nonfamilial dystonia |
| G24.3 | Spasmodic torticollis |
| G24.4 | Idiopathic orofacial dystonia |
| G24.5 | Blepharospasm |
| G24.8 | Other dystonia |
| G24.9 | Dystonia, unspecified |
| G25.89 | Other specified extrapyramidal and movement disorders [specified as organic writer's cramp] |
| G35 | Multiple sclerosis |
| G36.0 | Neuromyelitis optica |
| G37.0 | Diffuse sclerosis of central nervous system (Schilder's disease) |
| G37.5 | Concentric sclerosis [Balo] of central nervous system |
| G43.001-G43.919 | Migraine |
| G51.0-G51.9 | Facial nerve disorders |
| G80.0-G80.9 | Cerebral palsy |
| G81.10-G81.14 | Spastic hemiplegia |
| G83.4 | Cauda equina syndrome |
| G95.89 | Other specified diseases of spinal cord (cord bladder NOS) |
| H49.00-H49.9 | Paralytic strabismus |
| H50.00-H50.9 | Other strabismus |
| I69.00-I69.998 | Sequelae of cerebrovascular disease |
| J38.3 | Other diseases of vocal cords (spastic dysphonia) |
| J38.5 | Laryngeal spasm |
| K11.7 | Disturbance of salivary secretion |
| K22.0 | Achalasia of cardia (cardiospasm) |
| K60.0-K60.2 | Anal fissure |
| L74.510-L74.519 | Primary focal hyperhidrosis |
| L74.52 | Secondary focal hyperhidrosis |
| M43.6 | Torticollis |
| M62.838 | Other muscle spasm |
| N31.0-N31.9 | Neuromuscular dysfunction of bladder, not elsewhere classified |
| N32.81 | Overactive bladder (detrusor muscle hyperactivity) |
| N36.44 | Muscular disorders of urethra (bladder sphincter dyssynergy) |
| N39.3 | Stress incontinence |
| N39.41-N39.498 | Other specified urinary incontinence |
| Q43.1 | Hirschsprung's disease |
| Q68.0 | Congenital deformity of sternocleidomastoid muscle |
| R25.2 | Cramp and Spasm |
| R32 | Unspecified urinary incontinence |
| R49.8-R49.9 | Other and unspecified voice and resonance disorders |

| | |
|--------------------------|---|
| R61 | Generalized hyperhidrosis |
| S06.0X0S-S06.9X9S | Intracranial injury, sequela [code range, includes codes within this range with 7 th character 'S'] |
| S14.101S-S14.159S | Other and unspecified injury of cervical spinal cord [code range, includes codes within this range with 7 th character 'S'] |
| S24.101S-S24.159S | Other and unspecified injury of thoracic spinal cord [code range, includes codes within this range with 7 th character 'S'] |
| S34.101S-S34.139S | Other and unspecified injury of lumbar and sacral spinal cord [code range, includes codes within this range with 7 th character 'S'] |

Document History

Revised: 12/14/2020

Document History:

- 12/14/2020 – Select Review: Added may not be used criteria for botulinum use in continuation of therapy criteria for migraine headache to clarify botulinum toxin would not be used in conjunction with CGRP agents for prophylaxis of migraine headaches for either initiation of therapy OR continuation of therapy; Added diagnosis of Upper Limb Spasticity in pediatric patients 2 and older to diagnosis chart. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: Added may not be used criteria for botulinum use in migraine headache to indicate would not be used in conjunction with CGRP agents for prophylaxis; updated migraine initial indication to approve for 6 months and continuation of therapy for 1 year; Update dosing for botulinum toxin agents to indicate max dose for various indications per label and compendia along with maximum dispensed quantity based on vial size available. Coding Reviewed: No changes.
- 12/09/2019 – Select Review: Updated approved uses chart to indicate Dysport FDA approval for upper limb spasticity in children, Myobloc FDA approval for chronic sialorrhea, added line item in chart to delineate upper limb spasticity in children and adults. Coding reviewed: Added ICD-10 codes M62.838, and R25.2
- 09/23/2019 - Administrative update to add drug specific quantity limit.
- 05/17/2019 – Annual Review: Update approved uses chart to indicate Xeomin new indication as first line therapy for blepharospasm (removed requirement for Botox therapy first). Coding reviewed: no changes
- 11/09/2018 – Coding review, took out R13.10-R13.19 diagnosis for dysphagia to reflect removal of indication "disorder of the esophagus. Codes for dystonia no specific so kept in despite removal of cranial cervical dystonia indication. Indications removed: Cranial cervical dystonias, difficulty speaking – Total laryngectomy, disorder of esophagus, isolated promandibular dystonia, organic voice tremor, pelvic floor dystonia, spasm of pharyngoesophageal segment – Total laryngectomy. Remove duplicate HCPCS CPT codes: 52287, 64612, 64616, 62617, 62642, 62643, 62644, 62645, 62646, 64647.
- 8/18/2018 – Annual Review: Initial review of Botulinum Toxin. Updated chart to remove indications not supported by off-label policy and to add FDA labeled indications for Xeomin (new) and Botox (previously unlisted); Updated indications for dystonia/spasticity to include labeled indications of upper and lower limb spasticity; updated criteria elements for chronic migraine for consistency with P&T approved CGRP criteria and diagnostic criteria for migraine headaches.

References

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 9, 2020.
- DrugPoints@ System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
- Bellet JS; Diagnosis and treatment of primary focal hyperhidrosis in children and adolescents. Semin Cutan Med Surg. 2010; 29:121-126. Available from: <https://pdfs.semanticscholar.org/b8fd/2a80193355ede6543d90ea4bf61d36fbf831.pdf>.
- Simpson DM, Hallett M, Ashman EJ, 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.
- Diener HC, Dodick DW, Aurora SK, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. Cephalgia. 2010; 30(7):804-814.
- Aurora SK, Dodick DW, Turkel CC, et al.; PREEMPT 1 Chronic Migraine Study Group. Onabotulinumtoxin A for treatment of chronic migraine: Results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. Cephalgia 2010; 30(7):793-803.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic,

mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association