09-J0000-29

Original Effective Date: 10/15/99

Reviewed: 12/14/22

Revised: 01/15/23

Subject: Botulinum Toxins

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DESCRIPTION:

Botulinum toxin has been used for a wide variety of conditions in which the principal therapeutic aim is to reduce undesired or excessive contraction of striated or smooth (involuntary) muscle. There are five commercially available botulinum toxin type A preparations, onabotulinumtoxinA (Botox), incobotulinumtoxinA (Xeomin), abobotulinumtoxinA (Dysport), prabotulinumtoxinA (Jeuveau) and daxibotulinumtoxinA-lanm (Daxxify); and one botulinum toxin type B preparation, rimabotulinumtoxinB (Myobloc) available in the US. Jeuveau and Daxxify are indicated for cosmetic uses only. Because the potency of each botulinum toxin preparation is specific to the preparation and assay method, units of biologic activity for different preparations of botulinum toxin cannot be compared with or converted to units of other botulinum toxins. While therapy with botulinum toxin is relatively expensive considering the drug and administration costs and its effects are temporary and palliative (i.e., not curative) because of regeneration of nerve terminals in the affected muscle(s), treatment with botulinum toxin may provide an alternative to, or delay, more invasive and more costly interventions (e.g., surgery) and/or provide treatment for conditions for which few, if any, other effective therapies exist. Botulinum toxin also may be used in combination with other treatments to enhance efficacy. Because botulinum toxin prevents release of acetylcholine through denervation of cholinergic nerve terminals, the toxin also is used for autonomic disorders involving excessive glandular secretion (e.g., primary axillary hyperhidrosis) that is controlled by cholinergic transmission.

OnabotulinumtoxinA (Botox) is FDA-approved for the prophylaxis of headaches in adult patients with chronic migraine. The manufacturer conducted a double-blind, placebo-controlled study (NCT01662492) in adolescents aged 12 to 18 years with chronic migraine (migraines for longer than 6 months, with more than 15 headache days in a 4-week period) to assess efficacy in non-adult patients. Subjects were randomized to receive 155 units of Botox (n=45), 74 units of Botox (n=43), or placebo (normal saline) (n=37) over a 12-week trial. The mean change in frequency of headache days per 28-day period from

baseline was similar across all groups (placebo -6.8; 74 units of Botox -6.4; 155 units of Botox -6.3). There was no significant difference in percentage of patients with a 50% reduction or greater in frequency of headache days across groups (placebo 30%; 74 units of Botox 33%, 155 units of Botox 29%). No serious adverse events were seen in the placebo group. Serious adverse events were seen in 5% of those treated with 74 units of Botox (1 appendicitis, 1 migraine) and in 2% of those treated with 155 units of Botox (1 cellulitis). Other adverse events were reported in 22% of those treated with placebo, 32% of those treated with 74 units of Botox, and 19% of those treated with 155 units of Botox. The most common side effects seen more in treated groups were neck pain (9% of those receiving Botox vs.0% of those receiving placebo) and musculoskeletal pain (5% of those receiving Botox vs 0% of those receiving placebo).

POSITION STATEMENT:

Initiation of botulinum toxin [excluding prabotulinumtoxinA (Jeuveau) and daxibotulinumtoxinA-lanm (Daxxify)] **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1", "2", and "3"):

1. The drug is being administered for the treatment of an indication listed in Table 1, and **ALL** of the indication specific and maximum dose criteria are met
2. The botulinum toxin requested is **NOT** to be used concurrently with a different botulin toxin (even if they are to be used for different indications)
3. If a member is being treated for multiple indications, the total cumulative dosage across all indications must not exceed the following:
    a. Botox - 400 units every 12 weeks
    b. Dysport - 1,500 units every 12 weeks
    c. Myobloc - 15,000 units every 12 weeks
    d. Xeomin - 400 units every 12 weeks

TABLE 1:

Indications and Specific Criteria		
Neurologic		
Indication	**Criteria**	**Maximum Allowable Dose (per 12 weeks)**
Blepharospasm	When blepharospasm is characterized by intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle	Botox: 100 units (50 units per eye) [billing max of 100 units]

		Xeomin: 100 units (50 units per eye) [billing max of 100 units]
Cervical dystonia (including spasmodic torticollis)	When **ALL** of the following are met: • Cervical dystonia is associated with sustained head tilt **OR** abnormal posturing with limited range of motion in the neck • Member has a history of recurrent, involuntary contraction of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles) • Alternative causes of the member's symptoms have been ruled out (e.g., chronic neuroleptic treatment, contractures, or other neuromuscular disorders)	Botox: 300 units [billing max of 300 units] Dysport: • Initial: 500 units [billing max of 500 units] • Maintenance: 1,000 units [billing max of 1,000 units] Myobloc: 10,000 units [billing max of 10,000 units] Xeomin: 300 units [billing max of 300 units]
Essential tremor affecting the arms and/or hands	When **BOTH** of the following are met: • Member has had an inadequate response to at least 2 months of continuous treatment with or had an intolerance to at least **TWO** of the following, **OR** has contraindications to **ALL** of the following - if applicable, the specific intolerance(s) and/or contraindication(s) must be provided: o Propranolol (Inderal) o Primidone (Mysoline) o Alprazolam (Xanax) o Atenolol (Tenormin) o Clonazepam (Klonopin)	Botox: 200 units (100 each side) [billing max of 200 units] Xeomin: 200 units (100 each side) [billing max of 200 units]

	○ Gabapentin (Neurontin) ○ Topiramate (Topamax) ○ Sotalol (Betapace) • Condition results in significant functional impairment (e.g., affects activities of daily living, including writing and eating)	
Focal dystonias • Focal upper limb dystonia (e.g., organic writer's cramp) • Laryngeal dystonia (adductor/abductor spasmodic dysphonia) • Oromandibular dystonia • Orofacial dyskinesia • Cranial dystonia (Meige syndrome)	When **EITHER** of the following is met: • Condition results in significant functional impairment (e.g., interference with joint function, mobility, communication, nutritional intake) • Member experiences pain as a result of the condition	Botox: 360 units [billing max of 400 units] Xeomin: 400 units [billing max of 400 units]
Hemifacial spasm (seventh cranial nerve disorders)	Condition is characterized by sudden, unilateral, synchronous contractions of muscles innervated by the facial nerve	Botox: 25 units [billing max of 100 units] Xeomin: 25 units [billing max of 50 units]
Chronic migraine prophylaxis† in adults	When **ALL** of the following criteria are met: • Member is 18 years of age or older • Member meets **BOTH** of the following diagnostic criteria for chronic migraine – **supportive medical record documentation must be submitted, and must also include the specific number or an approximate range of patient-reported headache and migraine days in the prior month:**	Botox: 155 units [billing max of 200 units] Xeomin: 155 units [billing max of 200 units]

	○ Member has headaches for 15 or more days per month, each headache lasts for 4 hours or more, and duration is greater than 3 months ○ On at least 8 days (of the 15 days per month) per month for greater than 3 months, the headache is classified as migraine[†] with aura or without aura • The prescriber is a headache specialist (e.g. neurologist; pain management specialist; or specialist with United Council for Neurologic Subspecialties [UCNS] certification) or the prescriber has consulted with a headache specialist • **EITHER** of the following: ○ Member has had an inadequate response to at least 6 weeks of continuous treatment, at a generally accepted dose, with at least **ONE** medication selected from any of the following classes of migraine prophylaxis medications: - CGRP receptor antagonists FDA-approved for migraine prophylaxis [e.g., atogepant (Qulipta), eptinezumab (Vyepti), erenumab (Aimovig), fremanezumab (Ajovy), galcanezumab (Emgality), rimegepant (Nurtec)] - Non-SSRI antidepressants (e.g., amitriptyline, clomipramine, doxepin, mirtazapine, nortriptyline, venlafaxine) - Antiepileptics (e.g., divalproex, gabapentin, topiramate)	

	- Beta-blockers (e.g., atenolol, metoprolol, nadolol, propranolol, timolol); - Calcium channel blockers (e.g., diltiazem, nifedipine, nimodipine, verapamil) o Member has contraindications to **ALL** five classes of medications – the specific contraindications must be provided	
Spastic conditions affecting the upper and/or lower limbs • Cerebral palsy • Cerebrovascular accident (stroke) • Spinal cord injury • Traumatic brain injury • Hereditary spastic paraplegia • Multiple Sclerosis • Neuromyelitis optica • Schilder's disease • Spastic hemiplegia • Transverse myelitis • Demyelinating diseases of CNS	When **BOTH** of the following are met: • **EITHER** of the following: o Condition results in functional impairment (e.g., interference with joint function, mobility, communication, nutritional intake) o Member experiences pain as a result of the condition • Surgical intervention is considered to be the last option	Dysport: 1,500 units [billing max of 1,500 units] Botox: 400 units [billing max of 400 units] Xeomin: 400 units [billing max of 400 units]
Torsion dystonia (including primary/genetic (idiopathic) and acquired (symptomatic))	When **EITHER** of the following is met: • Condition results in functional impairment (e.g., interference with joint function, mobility, communication, nutritional intake) • Member experiences pain as a result of the condition	Botox: 360 units [billing max of 400 units] Xeomin: 360 units [billing max of 400 units]

Exocrine		
Indication	**Criteria**	**Maximum Allowable Dose (per 12 weeks)**
Primary hyperhidrosis affecting the palms of hands, soles of feet, and/or axilla	When **ALL** of the following are met: • Potential causes of secondary hyperhidrosis have been ruled out (e.g., hyperthyroidism) • Condition is refractory to at least 2 months of continuous treatment with a topical agent (e.g., ≥10% aluminum chloride) unless use results in severe dermatitis • **EITHER** of the following: o The condition is associated with significant functional impairment (e.g., member is unable to perform age-appropriate activities of daily living) o The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infections, secondary microbial infections)	Botox: 50 units per site, not to exceed 300 units if all six sites are affected • Palms of hands: two sites, 100 units total • Soles of feet: two sites, 100 units total • Axilla: two sites, 100 units total [billing max of 300 units] Xeomin: 50 units per site, not to exceed 300 units if all six sites are affected • Palms of hands: two sites, 100 units total • Soles of feet: two sites, 100 units total • Axilla: two sites, 100 units total [billing max of 300 units
Chronic sialorrhea (excessive salivation)	When **ALL** of the following are met: • Member has **ANY** of the following conditions: o Amyotrophic lateral sclerosis (ALS) o Atypical parkinsonian disorders o Cerebral palsy	Botox: • 100 units (e.g., 30 units to each parotid gland and 20 units to each submandibular gland) [billing max of 100 units]

	○ Parkinson disease (PD) ○ Stroke ○ Traumatic brain injury • Member has experienced excessive salivation for 3 or more months • Member is refractory to at least 2 months of continuous treatment with, had intolerable adverse effects with, or has a contraindication to at least one oral pharmacotherapy (e.g., anticholinergics) – if applicable, the specific intolerance or contraindication must be provided	Myobloc: • 3,500 units (e.g., 1,500 units to each parotid gland and 250 units to each submandibular gland) [billing max of 5,000units] Xeomin: • <27 kg (60 lbs.): 50 units [billing max of 50 units] • ≥27 kg (60 lbs.): 100 units (e.g., 30 units to each parotid gland and 20 units to each submandibular gland) [billing max of 100 units]
Gustatory sweating (e.g., Frey's Syndrome, diabetic gustatory sweating)	When **ALL** of the following are met: • Other potential causes of hyperhidrosis (e.g., hyperthyroidism) have been ruled out, or have been adequately treated • **EITHER** of the following: ○ The condition is associated with significant functional impairment (e.g., member is unable to perform age-appropriate activities of daily living) ○ The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infections, secondary microbial infections) • For gustatory sweating that is **NOT** Frey's syndrome – member has had	Botox: 65 units [billing max of 100 units] Xeomin: 65 units [billing max of 100 units]

	an inadequate response to treatment with at least 2 months of continuous treatment with a topical medication (e.g., ≥10% aluminum chloride or anticholinergic) unless use results in severe dermatitis	
Gastrointestinal		
Indication	**Criteria**	**Maximum Allowable Dose (per 12 weeks)**
Chronic anal fissure	Member has had an inadequate response to at least **ONE** of the following topical treatments: • Topical nitroglycerin • Topical calcium channel blocker (e.g., diltiazem, nifedipine)	Botox: 25 units [billing max of 100 units] Xeomin: 25 units [billing max of 50 units]
Esophageal achalasia	When **ALL** of the following are met: • The member's diagnosis has been confirmed by esophageal manometry • **EITHER** of the following is met: o Member has had an inadequate response to previous pneumatic dilation therapy or myotomy o Member is considered a poor candidate for dilation/myotomy as evidenced by **ONE** or more of the following - Sigmoid-shaped esophagus - Previous dilation-induced perforation - Epiphrenic diverticulum or hiatal hernia	Botox: 100 units [billing max of 100 units] Xeomin: 100 units [billing max of 100 units]

	- High risk for complications of myotomy or pneumatic dilation (e.g., member has esophageal reflux or perforation) - Member has a limited life expectancy	
Hirschsprung disease	When **ALL** of the following are met: • Member has obstructive symptoms caused by a non-relaxing internal anal sphincter • Member experienced symptoms following surgery for their disease	Botox: 100 units [billing max of 100 units] Xeomin: 100 units [billing max of 100 units]
Ophthalmologic		
Indication	**Criteria**	**Maximum Allowable Dose (per 12 weeks)**
Strabismus disorders in adults	When **BOTH** of the following are met: • **ONE** or more of the following characteristics are present: ○ Horizontal strabismus up to 50 prism diopters ○ Vertical strabismus ○ Persistent sixth nerve palsy of one month or longer • Member has one or more of the following symptoms: ○ Diplopia ○ Impaired depth perception ○ Impaired peripheral vision ○ Impaired ability to maintain fusion	Botox: 25 units [billing max of 100 units] Xeomin: 25 units [billing max of 50 units]
Strabismus disorders in children (including infantile esotropia)	Diagnosis only	Botox: 25 units [billing max of 100 units]

		Xeomin: 25 units [billing max of 50 units]
Urologic		
Indication	**Criteria**	**Maximum Allowable Dose (per 12 weeks)**
Urinary incontinence	When **ALL** of the following are met: • Condition is due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury or multiple sclerosis) that has been confirmed by urodynamic testing • Member has failure of behavioral therapy (e.g., bladder training, habit training, biofeedback, and pelvic muscle exercises) • **EITHER** of the following: o Member has had an inadequate response to at least 2 months of continuous treatment with or intolerance to at least **ONE** prescription antimuscarinic (e.g., oxybutynin [Ditropan, Ditropan XL], tolterodine [Detrol, Detrol LA] solifenacin [Vesicare], trospium [Sanctura, Sanctura XR], darifenacin [Enablex], fesoterodine [Toviaz]) – if applicable, the specific intolerance must be provided o Member has a documented contraindication to **ALL** oral antimuscarinics - the specific contraindication(s) must be provided	Botox: 200 units [billing max of 200 units] Xeomin: 200 units [billing max of 200 units]

Neurogenic detrusor overactivity
 	
[pediatric patients ONLY]
	When **ALL** of the following are met:
	
	• Member is at least 5 years of age but less than 18 years of age [refer to the urinary incontinence criteria above for adult members]
	
	• Condition is due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, spinal dysraphism such as spinal bifida) that has been confirmed by urodynamic testing
	
	• **EITHER** of the following:
	  ○ Member has had an inadequate response to at least 2 months of continuous treatment with or intolerance to at least **ONE** prescription antimuscarinic appropriate for pediatric use (e.g., oxybutynin [Ditropan, Ditropan XL], solifenacin [Vesicare], trospium [Sanctura, Sanctura XR]) – if applicable, the specific intolerance must be provided
	  ○ Member has documented contraindications to **BOTH** oxybutynin **AND** solifenacin - the specific contraindication(s) must be provided
		Botox:
		
		• <34 kg (75 lbs.): 6 units/kg
		
		[billing max of 100 units if 17 kg (37 lbs.) or less]
		
		[billing max of 200 units greater than 17 kg (37 lbs.)]
		
		• ≥34 kg (75 lbs.): 200 units
		
		[billing max of 200 units]

Overactive bladder (OAB)	When **ALL** of the following are met: • Member has symptoms of urge urinary incontinence, urgency, or frequency • Member has failure of behavioral therapy (e.g., bladder training, habit training, biofeedback, and pelvic muscle exercises) • **EITHER** of the following: ○ Member has had an inadequate response to at least 2 months of continuous treatment with or intolerance(s) to at least	Botox: 100 units [billing max of 100 units] Xeomin: 100 units [billing max of 100 units]

	TWO prescription antimuscarinics (e.g., oxybutynin [Ditropan, Ditropan XL], tolterodine [Detrol, Detrol LA] solifenacin [Vesicare], trospium [Sanctura, Sanctura XR], darifenacin [Enablex], fesoterodine [Toviaz]) – if applicable, the specific intolerance(s) must be provided ○ Member has documented contraindications to **ALL** oral antimuscarinics - the specific contraindication(s) must be provided	
Approval duration: 24 weeks †Diagnostic criteria for migraine with aura and without aura are located in the section entitled "OTHER."		

Continuation of botulinum toxin [excluding prabotulinumtoxinA (Jeuveau) and daxibotulinumtoxinA-lanm (Daxxify)] treatment **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "6"):

1. Authorization or reauthorization has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of for an indication listed in Table 1, **OR** the member previously met **ALL** indication-specific initiation criteria.
2. Member has demonstrated a beneficial response to therapy.
3. For chronic migraine prophylaxis **ONLY** – Member has had a beneficial response to therapy as evidenced by following:
   - Less than 12 months of treatment – **EITHER** of the following ("i" or "ii"):
     i. Headache frequency was reduced by 7 days per month or more (when compared to pre-treatment average) by the end of the initial trial
     ii. Headache duration was reduced by 100 total hours per month or more (when compared to pre-treatment average) by the end of the month
   - 12 or more months of treatment – the member continues to maintain a clinically meaningful reduction in headache frequency and/or headache duration
4. The botulinum toxin requested is **NOT** to be used concurrently with a different botulin toxin (even if they are to be used for different indications)
5. If a member is being treated for multiple indications, the total cumulative dosage across all indications must not exceed the following, **unless** previously approved by Florida Blue:

a. Botox - 400 units every 12 weeks
b. Dysport - 1,500 units every 12 weeks
c. Myobloc - 15,000 units every 12 weeks
d. Xeomin - 400 units every 12 weeks

6. The dosage does not exceed the following in Table 2 based on the specific product and indication for use.

TABLE 2:

Indication	Maximum Allowable Dose (per 12 weeks)
Blepharospasm	Botox: 100 units (50 units per eye) [billing max of 100 units] Xeomin: 100 units (50 units per eye) [billing max of 100 units]
Cervical dystonia (including spasmodic torticollis)	Botox: 300 units [billing max of 300 units] Dysport: Initial: 500 units [billing max of 500 units] Maintenance: 1,000 units Myobloc:15,000 units [billing max of15,000 units] Xeomin: 300 units [billing max of 300 units]
Essential tremor of arm and/or hands	Botox: 200 units (100 each side) [billing max of 200 units] Xeomin: 200 units (100 each side) [billing max of 200 units]
Focal dystonias • Focal upper limb dystonia (e.g., organic writer's cramp) • Laryngeal dystonia (adductor/abductor spasmodic dysphonia) • Oromandibular dystonia	Botox: 360 units [billing max of 400 units] Xeomin: 400 units [billing max of 400 units]

• Orofacial dyskinesia • Cranial dystonia (Meige syndrome)	
Hemifacial spasm (seventh cranial nerve disorders)	Botox: 25 units [billing max of 100 units] Xeomin: 25 units [billing max of 50 units]
Chronic migraine prophylaxis	Botox: 155 units [billing max of 200 units] Xeomin: 155 units [billing max of 200 units]
Spastic conditions affecting the upper or lower limbs • Cerebral palsy • Cerebrovascular accident (stroke) • Spinal cord injury • Traumatic brain injury • Hereditary spastic paraplegia • Multiple Sclerosis • Neuromyelitis optica • Schilder's disease • Spastic hemiplegia • Transverse myelitis • Demyelinating diseases of CNS	Dysport: 1,500 units [billing max of 1,500 units] Botox: 400 units [billing max of 400 units] Xeomin: 400 units [billing max of 400 units]
Torsion dystonia (including primary/genetic (idiopathic) and acquired (symptomatic))	Botox: 360 units [billing max of 400 units] Xeomin: 360 units [billing max of 400 units]
Primary hyperhidrosis affecting the palms of hands, soles of feet, and/or axilla	Botox: 50 units per site, not to exceed 300 units if all six sites are affected • Palms of hands: two sites, 100 units total • Soles of feet: two sites, 100 units total • Axilla: two sites, 100 units total [billing max of 300 units] Xeomin: 50 units per site, not to exceed 300 units if all six sites are affected • Palms of hands: two sites, 100 units total

	• Soles of feet: two sites, 100 units total • Axilla: two sites, 100 units total [billing max of 300 units]
Chronic sialorrhea (excessive salivation) due to amyotrophic lateral sclerosis (ALS), atypical parkinsonian disorder, cerebral palsy, Parkinson disease (PD), stroke, or traumatic brain injury	Botox: • 100 units* (e.g., 30 units to each parotid gland and 20 units to each submandibular gland) [billing max of 100 units] Myobloc: • 3,500 units* (e.g., 1,500 units to each parotid gland and 250 units to each submandibular gland) [billing max of 5,000 units] Xeomin: • <27 kg (60 lbs.): 50 units* [billing max of 50 units] • ≥27 kg (60 lbs.): 100 units* (e.g., 30 units to each parotid gland and 20 units to each submandibular gland) [billing max of 100 units] **A higher dose may be approved if the dose was previously approved via clinical review and authorization by Florida Blue.*
Gustatory sweating (e.g., Frey Syndrome, diabetic gustatory sweating)	Botox: 65 units [billing max of 100 units] Xeomin: 65 units [billing max of 100 units]
Chronic anal fissure	Botox: 25 units [billing max of 100 units] Xeomin: 25 units [billing max of 50 units]
Esophageal achalasia	Botox: 100 units [billing max of 100 units] Xeomin: 100 units [billing max of 100 units]
Hirschsprung disease	Botox: 100 units [billing max of 100 units]

	Xeomin: 100 units [billing max of 100 units]
Strabismus disorders in adults	Botox: 25 units [billing max of 100 units] Xeomin: 25 units [billing max of 50 units]
Strabismus disorders in children (including infantile esotropia)	Botox: 25 units [billing max of 100 units] Xeomin: 25 units [billing max of 50 units]
Overactive bladder (OAB)	Botox: 100 units [billing max of 100 units] Xeomin: 100 units [billing max of 100 units]
Neurogenic detrusor overactivity [pediatric patients ONLY (<18 years of age)]	Botox: • <34 kg (75 lbs.): 6 units/kg [billing max of 100 units if 17 kg (37 lbs.) or less] [billing max of 200 units greater than 17 kg (37 lbs.)] • ≥34 kg (75 lbs.): 200 units [billing max of 200 units
Urinary incontinence	Botox: 200 units [billing max of 200 units] Xeomin: 200 units [billing max of 200 units]
Approval duration: 24 weeks	

Botulinum toxin for the treatment chronic migraines in non-adults (i.e., patients less than 18 years of age) **does NOT meet the definition of medical necessity** based on lack of efficacy including data from a 12-week, multicenter, double-blind, placebo-controlled clinical trial showing that onabotulinumtoxinA (Botox) was no more effective than placebo [see Section 8.4 in the Botox Prescribing Information].

Botulinum toxin is considered **experimental or investigational** when administered for all other indications as additional controlled clinical trials are needed to demonstrate the safety and efficacy and there is insufficient clinical evidence to support it use, and specifically for the following:

- Anal spasm
- Anal sphincter dysfunction
- Bell's Palsy
- Benign essential tremor
- Benign prostatic hyperplasia (BPH)
- Biliary dyskinesia (Sphincter of Oddi dysfunction)
- Blepharoplasty
- Carpel tunnel syndrome
- Chronic motor tic disorder
- Chronic pain, chronic low back pain, chronic neck pain
- Clubfoot
- Depression
- Drooling (except chronic sialorrhea associated with ALS, atypical parkinsonian disorders, cerebral palsy, Parkinson disease, stroke, or traumatic brain injury)
- Episodic migraines
- Facial wound healing
- Fibromyositis/fibromyalgia
- Gastroparesis
- Interstitial cystitis
- Irritable colon
- Joint pain
- Lateral epicondylitis (tennis elbow)
- Mechanical neck disorders
- Myasthenia gravis
- Myofascial pain syndrome
- Neuropathic pain after neck dissection
- Non-migraine headaches
- Nystagmus
- Pain after hemorrhoidectomy or lumpectomy
- Painful cramps
- Parkinson's disease
- Prevention of pain associated with breast reconstruction after mastectomy
- Secondary hyperhidrosis
- Stuttering
- Temporomandibular joint (TMJ) disorders

- Tinnitus
- Vaginismus

The use of botulinum toxin [including prabotulinumtoxinA (Jeuveau) and daxibotulinumtoxinA-lanm (Daxxify)] administered for the treatment of skin wrinkles (e.g., glabellar creases, smoker's lines, lipstick lines, crow's feet, laugh lines, wrinkled neck, and aging neck) **does NOT meet the definition of medical necessity**, as they are considered cosmetic in nature and generally contract excluded.

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

TABLE 3:

FDA-approved indications† and Dosing		
Product	**FDA-approved Indications**	**Dose**
Botox	Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication	200 Units, as separate1 mL injections across 30 sites into detrusor
	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	100 Units, as separate 0.5 mL injections across 20 sites into detrusor
	Neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication	If 34 kg (75 lbs.) or greater, 200 Units as separate 0.5 mL injections across 20 sites into detrusor If less than 34 kg (75 lbs.), 6 Units/kg body weight given as injections across 20 sites into detrusor. Refer to product labeling for a table of dilution instructions and final dosing based on patient weight.

	Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)	155 Units, as 0.1 mL injections per each site divided across 7 head/neck muscles
	Spasticity in patients 2 years of age and older (includes upper and lower limbs) Limitations of Use: Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.	Adult: Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, or adverse event history. The lowest recommended starting dose should be used, and no more than 50 Units per site should generally be administered. For upper limb spasticity, in clinical trials, doses ranging from 75 Units to 400 Units were divided among selected muscles. The recommended dose for treating lower limb spasticity is 300 Units to 400 Units divided among 5 muscles (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus and flexor digitorum longus. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 Units, in a 3-month interval. Pediatric: The recommended dose for the upper limbs is 3 to 6 Units/kg divided among the affected muscles. The total dose administered per treatment session in the upper limb should not exceed 6 Units/kg or 200 Units, whichever is lower. The recommended dose for the lower limbs is 4 to 8 units/kg divided among the affected muscles. The total dose administered per treatment session in the lower limb should not exceed 8 Units/kg or 300 Units, whichever is lower. When treating both lower limbs or the upper and lower limbs in combination, the total dose should not

		exceed the lower of 10 Units/kg or 340 Units, in a 3-month interval.
	Cervical dystonia in adults	Base dosing on the member's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history
	Severe primary axillary hyperhidrosis in adults that is inadequately managed with topical agents	50 Units per axilla
	Blepharospasm associated with dystonia (12 years of age and older)	1.25 Units to 2.5 Units into each of 3 sites per affected eye
	Strabismus (12 years of age and older)	1.25 Units to 2.5 Units in any one muscle
Dysport	Cervical dystonia in adults	500 Units as a divided dose among affected muscles. Doses above 1000 Units have not been systematically evaluated.
	Spasticity in patients 2 years of age and older (upper and lower limbs)	Dosing should be tailored based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, and/or adverse reaction history with botulinum toxins. Dosing in clinical trials for upper limb spasticity in adults was between 500 Units and 1000 Units and for lower limb spasticity was between 1000 Units and 1500 Units. The maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 Units. Refer to the package labeling for dosing in pediatric patients.
Myobloc	Cervical dystonia in adults	Recommended initial dosage is 2,500 to 5,000 Units divided among affected muscles in members with a history of tolerating botulinum toxin injections. Patients without a prior history of tolerating botulinum toxin

		injections should receive a lower initial dosage. Subsequent dosing should be determined by the patient's individual response.
	Chronic sialorrhea in adults	Recommended dosage is 1,500 Units to 3,500 Units divided among the parotid (500 to 1,500 Units per gland) and submandibular glands (250 Units per gland)
Xeomin	Cervical dystonia in adults	Recommended initial dosage is 120 Units per treatment session. In previously treated patients, their past dose, response to treatment, duration of effect, and adverse event history should be taken into consideration when determining the dose. The frequency of repeat treatments should be determined by clinical response but should generally be no more frequent than every 12 weeks.
	Blepharospasm in adults	In treatment-naïve patients, the recommended initial total dose is 50 Units (25 Units per eye). In patients previously treated with abotulinumtoxinA, their past dose, response to treatment, duration of effect, and adverse event history should be taken into consideration when determining the dose. The total dose should not exceed 100 Units per treatment session (50 Units per eye).
	Upper limb spasticity in adults	The dosage, frequency, and number of injection sites should be tailored to the individual patient based on the size, number, and location of muscles to be treated, severity of spasticity, presence of local muscle weakness, prior response to treatment, and adverse event history. In patients not previously treated with a botulinum toxin, initial dosing should begin at the low end of the recommended dosing range and titrated as clinically necessary. In clinical trials, doses up to 400 Units were

		divided among selected muscles and most patients were retreated between 12 and 14 weeks.
	Upper limb spasticity in pediatric patients (2 to 17 years of age), excluding spasticity caused by cerebral palsy	The exact dosage, frequency, and number of injection sites should be tailored to the individual patient based on size, number and localization of involved muscles; the severity of spasticity; and the presence of local muscle weakness. The maximum recommended dose is 8 Units/kg, divided among affected muscles, up to a maximum dose of 200 Units per single upper limb. If both upper limbs are treated, the total dosage should not exceed 16 Units/kg, up to a maximum of 400 Units. The timing for repeat treatment should be determined based on the clinical need of the patient; the frequency of repeat treatments should be no sooner than every 12 weeks. Most patients in clinical studies were retreated between 12 and 16 weeks.
	Chronic sialorrhea in patients 2 years of age and older	Recommended total dose per treatment session in adults (≥18 years of age) is 100 Units (i.e., 30 Units for each parotid gland and 20 Units for each submandibular gland). For pediatric patients (2 to 17 years of age), the dose is weight-based with total doses ranging from 20 to 75 Units per treatment session. Only children 27 kg (60 lbs.) or greater require a dose above 50 Units. Xeomin has not been studied in children weighing less than 12 kg. Refer to the package labeling for specific dosing recommendations. For both adults and children, repeat treatment should be determined based on the actual clinical need of the individual patient, and no sooner than every 16 weeks.
[†]Indications related to cosmetic procedures (e.g., reduction in appearance of glabellar lines) are not provided in this table.		

Drug Availability

- Botox: available as a single-use, sterile 100 Unit or 200 Unit vacuum-dried powder for reconstitution. Only Botox Cosmetic is available in a 50 Unit vial size.
- Dysport: available as a single-use, sterile 300 Unit or 500 Unit vial for reconstitution
- Myobloc: available as a single-use in 2,500; 5,000; and 10,000 Unit sterile glass vials
- Xeomin: available as a single-use, sterile 50 Unit, 100 Unit, and 200 Unit vial for reconstitution

PRECAUTIONS:

Boxed Warning:

Postmarketing reports indicate that the effects of Botox and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include 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 of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses.

Contraindications

All products

- Hypersensitivity to any botulinum toxin preparation or to any of the components of the formulation
- Infection at the proposed injection site

Botox

- Intradetrusor Injections: acute urinary tract infection and/or acute urinary retention

Dysport

- Allergy to cow's milk protein

Warnings

- The potency units of botulinum toxin products are not interchangeable
- Care should be exercised when injecting in or near vulnerable anatomic structures
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment
- Use in caution in members with compromised respiratory function
- Corneal exposure and ulceration due to reduced blinking may occur when products are used for the treatment of blepharospasm
- Retrobulbar hemorrhages and compromised retinal circulation may occur when products are used for the treatment of strabismus

- Bronchitis and upper respiratory tract infections may occur when products are used for the treatment of limb spasticity
- Urinary retention: post-void residual urine volume should be monitored in members treated for detrusor overactivity associated with a neurologic condition who do not catheterize routinely, particularly in members with multiple sclerosis.
- Products contain human albumin; a theoretical risk for transmission of viral diseases and/or Creutzfeldt-Jakob disease (CJD) is possible but is considered extremely remote. No cases of transmission of either have ever been identified in association with licensed albumin or albumin contained in other licensed products.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding:

J0585	Injection, onabotulinumtoxinA, 1 unit (Botox®)
J0586	Injection, abobotulinumtoxinA, 5 units (Dysport®)
J0587	Injection, rimabotulinumtoxinB, 100 units (Myobloc®)
J0588	Injection, incobotulinumtoxinA, 1 unit (Xeomin®)

ICD-10 Diagnosis Codes That Support Medical Necessity of Botox (J0585) and Xeomin (J0588):

G11.4	Hereditary spastic paraplegia
G24.1	Genetic torsion dystonia
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G24.8	Other dystonia
G25.89	Other specified extrapyramidal and movement disorders
G35	Multiple sclerosis
G36.0	Neuromyelitis optica
G37.0	Diffuse sclerosis of central nervous system
G37.1	Central demyelination of corpus callosum
G37.2	Central pontine myelinolysis
G37.3	Acute transverse myelitis in demyelinating disease of central nervous system
G37.5	Concentric sclerosis [Balo] of central nervous system
G37.8	Other specified demyelinating diseases of central nervous system
G37.9	Demyelinating disease of central nervous system, unspecified
G43.001 – G43.009	Migraine without aura, not intractable
G43.011 – G43.019	Migraine without aura, intractable
G43.101 – G43.109	Migraine with aura, not intractable
G43.111 – G43.119	Migraine with aura, intractable
G43.401 – G43.409	Hemiplegic migraine, not intractable
G43.411 – G43.419	Hemiplegic migraine, intractable
G43.501 – G43.509	Persistent migraine aura without cerebral infarction, not intractable

G43.511 – G43.519	Persistent migraine aura without cerebral infarction, intractable
G43.601 – G43.609	Persistent migraine aura with cerebral infarction, not intractable
G43.611 – G43.619	Persistent migraine aura with cerebral infarction, intractable
G43.701 – G43.709	Chronic migraine without aura, not intractable
G43.711 – G43.719	Chronic migraine without aura, intractable
G43.801 – G43.809	Other migraine, not intractable
G43.811 – G43.819	Other migraine, intractable
G43.821 – G43.829	Menstrual migraine, not intractable
G43.831 – G43.839	Menstrual migraine, intractable
G43.901 – G43.909	Migraine, unspecified, not intractable
G43.911 – G43.919	Migraine, unspecified, intractable
G43.A0 – G43.A1	Cyclical vomiting
G43.B0 – G43.B1	Ophthalmoplegic migraine
G43.C0 – G43.C1	Periodic headache syndromes in child or adult
G43.D0 – G43.D1	Abdominal migraine
G44.221	Chronic tension-type headache, intractable
G44.229	Chronic tension-type headache, not intractable
G51.2	Melkersson syndrome
G51.4	Facial myokymia
G51.8	Other disorders of facial nerve
G80.0 – G80.9	Cerebral palsy
G81.10 – G81.14	Spastic hemiplegia
G82.20 – G82.22	Paraplegia
G82.50 – G82.54	Quadriplegia
G83.0	Diplegia of upper limbs
G83.20 – G83.24	Monoplegia of upper limb
G83.4	Cauda equina syndrome
G83.81	Brown-Sequard syndrome
G83.82	Anterior cord syndrome
G83.89	Other specified paralytic syndromes
H02.049	Spastic entropion of unspecified eye, unspecified eyelid
H02.149	Spastic ectropion of unspecified eye, unspecified eyelid
H49.00 – H49.03	Third [oculomotor] nerve palsy
H49.10 – H49.13	Fourth [trochlear] nerve palsy
H49.20 – H49.23	Sixth [abducent] nerve palsy
H49.30 – H49.33	Total (external) ophthalmoplegia
H49.40 – H49.43	Total (external) ophthalmoplegia
H49.881 – H49.889	Other paralytic strabismus
H49.9	Unspecified paralytic strabismus
H50.00	Unspecified esotropia
H50.011 – H50.012	Monocular esotropia
H50.021 – H50.022	Monocular esotropia with A pattern
H50.031 – H50.032	Monocular esotropia with V pattern

H50.041 – H50.042	Monocular esotropia with other noncomitancies
H50.05	Alternating esotropia
H50.06	Alternating esotropia with A pattern
H50.07	Alternating esotropia with V pattern
H50.08	Alternating esotropia with other noncomitancies
H50.10	Unspecified exotropia
H50.111 – H50.112	Monocular exotropia
H50.121 – H50.122	Monocular exotropia with A pattern
H50.131 – H50.132	Monocular exotropia with V pattern
H50.141 – H50.142	Monocular exotropia with other noncomitancies
H50.15	Alternating exotropia
H50.16	Alternating exotropia with A pattern
H50.17	Alternating exotropia with V pattern
H50.18	Alternating exotropia with other noncomitancies
H50.21 – H50.22	Vertical strabismus
H50.30	Unspecified intermittent heterotropia
H50.311 – H50.312	Intermittent monocular esotropia
H50.32	Intermittent alternating esotropia
H50.331 – H50.332	Intermittent monocular exotropia
H50.34	Intermittent alternating exotropia
H50.40	Unspecified heterotropia
H50.411 – H50.412	Cyclotropia
H50.42	Monofixation syndrome
H50.43	Accommodative component in esotropia
H50.50	Unspecified heterophoria
H50.51	Esophoria
H50.52	Exophoria
H50.53	Vertical heterophoria
H50.54	Cyclophoria
H50.55	Alternating heterophoria
H50.60	Mechanical strabismus unspecified
H50.611 – H50.612	Brown's sheath syndrome
H50.69	Other mechanical strabismus
H50.811 – H50.812	Duane's syndrome
H50.89	Other specified strabismus
H50.9	Unspecified strabismus
H51.0	Palsy (spasm) of conjugate gaze
H51.11 – H51.12	Convergence insufficiency and excess
H51.20 – H51.23	Internuclear ophthalmoplegia
H51.8	Other specified disorders of binocular movement
I69.031 – I69.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage
I69.041 – I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage
I69.051 – I69.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage

I69.061 – I69.069	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage
I69.131 – I69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage
I69.141 – I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage
I69.151 – I69.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage
I69.161 – I69.169	Other paralytic syndrome following nontraumatic intracerebral hemorrhage
I69.231 – I69.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage
I69.241 – I69.249	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage
I69.251 – I69.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage
I69.261 – I69.269	Other paralytic syndrome following other nontraumatic intracranial hemorrhage
I69.331 – I69.339	Monoplegia of upper limb following cerebral infarction
I69.341 – I69.349	Monoplegia of lower limb following cerebral infarction
I69.351 – I69.359	Hemiplegia and hemiparesis following cerebral infarction
I69.361 – I69.369	Other paralytic syndrome following cerebral infarction
I69.831 – I69.839	Monoplegia of upper limb following other cerebrovascular disease
I69.841 – I69.849	Monoplegia of lower limb following other cerebrovascular disease
I69.851 – I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease
I69.861 – I69.869	Hemiplegia and hemiparesis following other cerebrovascular disease
I69.931 – I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease
I69.941 – I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease
I69.951 – I69.959	Hemiplegia and hemiparesis following unspecified cerebrovascular disease
I69.961 – I69.969	Other paralytic syndrome following unspecified cerebrovascular disease
J38.5	Laryngeal spasm
K11.7	Disturbance of salivary secretion
K22.0	Achalasia of cardia
K22.5	Diverticulum of esophagus, acquired
K44.9	Diaphragmatic hernia without obstruction or gangrene
K60.2	Anal fissure, unspecified
L74.510	Primary focal hyperhidrosis, axilla
L74.511	Primary focal hyperhidrosis, face
L74.512	Primary focal hyperhidrosis, palms
L74.513	Primary focal hyperhidrosis, soles
L74.519	Primary focal hyperhidrosis, unspecified
L74.52	Secondary focal hyperhidrosis
M43.6	Torticollis
M62.40	Contracture of muscle, unspecified site
M62.838	Other muscle spasm
N31.8	Other neuromuscular dysfunction of bladder
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder

N36.44	Muscular disorders of urethra
N39.41	Urge incontinence
N39.46	Mixed incontinence
N39.492	Postural (urinary) incontinence
Q43.1	Hirschsprung's disease
R35.0	Frequency of micturition
R49.0	Dysphonia
R49.8	Other voice and resonance disorders
R68.2	Dry mouth, unspecified
S04.9XXS	Injury of unspecified cranial nerve, sequel
S06.9X9S	Unspecified intracranial injury with loss of consciousness of unspecified duration, sequel
S14.109S	Unspecified injury at unspecified level of cervical spinal cord, sequel
S14.2XXS	Injury of nerve root of cervical spine, sequela
S14.9XXS	Injury of unspecified nerves of neck, sequel
S24.109S	Unspecified injury at unspecified level of thoracic spinal cord, sequela
S24.2XXS	Injury of nerve root of thoracic spine, sequel
S24.9XXS	Injury of unspecified nerve of thorax, sequel
S34.109S	Unspecified injury to unspecified level of lumbar spinal cord, sequela
S34.139S	Unspecified injury to sacral spinal cord, sequela
S34.21XS	Injury of nerve root of lumbar spine, sequel
S34.22XS	Injury of nerve root of sacral spine, sequel
S34.9XXS	Injury of unspecified nerves at abdomen, lower back and pelvis level, sequela

ICD-10 Diagnosis Codes That Support Medical Necessity of Dysport (J0586):

G11.4	Hereditary spastic paraplegia
G24.3	Spasmodic torticollis
G25.89	Other specified extrapyramidal and movement disorders
G35	Multiple sclerosis
G36.0	Neuromyelitis optica
G37.0	Diffuse sclerosis of central nervous system
G37.1	Central demyelination of corpus callosum
G37.2	Central pontine myelinolysis
G37.3	Acute transverse myelitis in demyelinating disease of central nervous system
G37.5	Concentric sclerosis [Balo] of central nervous system
G37.8	Other specified demyelinating diseases of central nervous system
G37.9	Demyelinating disease of central nervous system, unspecified
G80.0 – G80.9	Cerebral palsy
G81.10 – G81.14	Spastic hemiplegia
G82.20 – G82.22	Paraplegia
G82.50 – G82.54	Quadriplegia
G83.0	Diplegia of upper limbs
G83.20 – G83.24	Monoplegia of upper limb

G83.4	Cauda equina syndrome
G83.81	Brown-Sequard syndrome
G83.82	Anterior cord syndrome
G83.89	Other specified paralytic syndromes
I69.031 – I69.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage
I69.041 – I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage
I69.051 – I69.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage
I69.061 – I69.069	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage
I69.131 – I69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage
I69.141 – I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage
I69.151 – I69.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage
I69.161 – I69.169	Other paralytic syndrome following nontraumatic intracerebral hemorrhage
I69.231 – I69.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage
I69.241 – I69.249	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage
I69.251 – I69.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage
I69.261 – I69.269	Other paralytic syndrome following other nontraumatic intracranial hemorrhage
I69.331 – I69.339	Monoplegia of upper limb following cerebral infarction
I69.341 – I69.349	Monoplegia of lower limb following cerebral infarction
I69.351 – I69.359	Hemiplegia and hemiparesis following cerebral infarction
I69.361 – I69.369	Other paralytic syndrome following cerebral infarction
I69.831 – I69.839	Monoplegia of upper limb following other cerebrovascular disease
I69.841 – I69.849	Monoplegia of lower limb following other cerebrovascular disease
I69.851 – I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease
I69.861 – I69.869	Hemiplegia and hemiparesis following other cerebrovascular disease
I69.931 – I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease
I69.941 – I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease
I69.951 – I69.959	Hemiplegia and hemiparesis following unspecified cerebrovascular disease
I69.961 – I69.969	Other paralytic syndrome following unspecified cerebrovascular disease
M43.6	Torticollis
S14.109S	Unspecified injury at unspecified level of cervical spinal cord, sequel
S14.2XXS	Injury of nerve root of cervical spine, sequela
S14.9XXS	Injury of unspecified nerves of neck, sequel
S24.109S	Unspecified injury at unspecified level of thoracic spinal cord, sequela
S24.2XXS	Injury of nerve root of thoracic spine, sequel
S24.9XXS	Injury of unspecified nerve of thorax, sequel
S34.109S	Unspecified injury to unspecified level of lumbar spinal cord, sequela
S34.139S	Unspecified injury to sacral spinal cord, sequela
S34.21XS	Injury of nerve root of lumbar spine, sequel
S34.22XS	Injury of nerve root of sacral spine, sequel

S34.9XXS	Injury of unspecified nerves at abdomen, lower back and pelvis level, sequela

ICD-10 Diagnosis Codes That Support Medical Necessity of Myobloc (J0587):

G24.3	Spasmodic torticollis
K11.7	Disturbance of salivary secretion
M43.6	Torticollis
R68.2	Dry mouth, unspecified

REIMBURSEMENT INFORMATION:

Injection of the vocal cords is done as an integral part of laryngoscopic guidance (31513, 31570, 31571), therefore does not warrant separate billing of the laryngoscope and injection.

Injection for treatment of achalasia requires a separate endoscopy procedure, which is billed and reimbursed separately.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products:

No National Coverage Determination (NCD) was found at the time of the last guideline reviewed date.

The following Local Coverage Determination (LCD) located at www.fcso.com was reviewed on the last guideline reviewed date:

- Botulinum toxins, (L33274)

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

DEFINITIONS:

Abductor: any muscle that moves one part of the body away from another or away from the middle of the body.

Achalasia: idiopathic motility disorder of the esophagus characterized by a lack of peristalsis in the esophageal body and absent or incomplete relaxation of the lower esophageal sphincter (LES). There is no curative therapy for achalasia and both surgical (e.g., myotomy, pneumatic dilation) and nonsurgical palliative treatment modalities (e.g., botulinum toxin) have been developed with the aim of decreasing the LES pressure, thus facilitating esophageal emptying.

Anal fissure: tear in the anus

Axillary: armpit area

Blepharoplasty: any operation for the correction of a defect in the eyelids.

Blepharospasm: a twitching or spasmodic contraction of the orbicularis oculi muscle due to habit spasm, eyestrain, or nervous irritability.

Diverticulum: small pouch in the colon

Dyskinesia: involuntary movement

Dysphonia: any disorder with speech affecting voice quality or ability to produce voice.

Dystonia: a more general term describing a state of abnormal or disordered tonicity of muscle. Achalasia is an example of dystonia of the lower esophageal sphincter; cervical dystonia is also known as torticollis.

Esotropia: one or both eyes turning inward

Frey's Syndrome (gustatory sweating): redness and sweating on the cheek area adjacent to the ear.

Hiatal hernia: the protrusion of the upper part of the stomach into the thorax through a tear or weakness in the diaphragm.

Hyperhidrosis: excessive sweating.

Oromandibular dystonia: characterized by continuous, bilateral, asynchronous muscle spasms in the face, jaw, pharynx, and tongue causing difficulty in jaw closing or opening and interfering with fluid and food intake and speech; muscles of the neck, larynx, and respiratory system may be involved in severe cases.

Palmar: relating to the palm of the hand

Myotomy: surgical procedure in which muscle is cut. A common example of a myotomy is the Heller myotomy in which muscles of the cardia (lower esophageal sphincter or LES) are cut, allowing for food and liquids to pass to the stomach. It is used to treat achalasia.

Neuromyelitis optica: an inflammatory demyelinating disorder of the CNS in which the immune system attacks the optic nerves and spinal cord.

Pneumatic dilation: type of esophageal dilation in which a balloon is inserted in the deflated form into the area of narrowing. It is then inflated with air to a certain pressure that is pre-set for a given circumference.

Schilder's disease: a subacute or chronic form of leukoencephalopathy of children and adolescents.

Spasm: a sudden involuntary contraction of one or more muscle groups; includes cramps and contractures.

Spasticity: a disorder of muscle tone that occurs as the result of a variety of injuries to the central nervous system; characterized by a velocity-dependent increase in tonic-stretch reflexes with exaggerated tendon jerks.

Sternocleidomastoid: pertaining to the sternum, clavicle and mastoid process.

Strabismus: a visual disorder in which one eye cannot align with the other.

Torticollis: congenital or acquired stiff neck caused by spasmodic contraction of the neck muscles, drawing the head to one side with the chin pointing to the other side.

RELATED GUIDELINES:

Treatment of Hyperhidrosis, 01-94010-08

OTHER:

Migraine without aura diagnostic criteria

A. At least five attacks fulfilling criteria B to D
B. Headache attacks lasting 4 to 72 hours (untreated or unsuccessfully treated)
C. Headache has at least two of the following four characteristics:
    1. Unilateral location
    2. Pulsating quality
    3. Moderate or severe pain intensity
    4. Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)
D. During headache at least one of the following:
    1. Nausea and/or vomiting
    2. Photophobia and phonophobia
E. Not better accounted for by another ICHD-3 diagnosis.

Migraine with aura diagnostic criteria

A. At least two attacks fulfilling criteria B and C
B. One or more of the following fully reversible aura symptoms:
    1. Visual
    2. Sensory
    3. Speech and/or language
    4. Motor
    5. Brainstem
    6. Retinal
C. At least three of the following six characteristics:
    1. At least one aura symptom spreads gradually over ≥5 minutes
    2. Two or more symptoms occur in succession
    3. Each individual aura symptom lasts 5 to 60 minutes

4. At least one aura symptom is unilateral
5. At least one aura symptom is positive
6. The aura is accompanied, or followed within 60 minutes, by headache

D. Not better accounted for by another ICHD-3 diagnosis

Chronic Migraine diagnostic criteria

A. Headache (tension-type-like and/or migraine-like) on ≥15 days per month for >3 months and fulfilling criteria B and C

B. Occurring in a patient who has had at least five attacks fulfilling criteria B to D for Migraine without aura and/or criteria B and C for Migraine with aura

C. On ≥8 days per month for >3 months, fulfilling any of the following:

1. Criteria C and D for Migraine without aura
2. Criteria B and C for Migraine with aura
3. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative

D. Not better accounted for by another ICHD-3 diagnosis.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 12/14/22.

GUIDELINE UPDATE INFORMATION:

10/15/99	Medical Coverage Guideline Reformatted.
01/01/01	Coding changes.
07/15/01	Revised.
01/01/02	Coding changes.
01/01/03	HCPCS coding update.
03/15/03	Moved Botox information from section entitled “Other” to “When Services are Covered”.
12/15/03	Reviewed, revised to include criteria for covered indications; covered and non-covered indications expanded.
01/01/05	Added new primary axillary hyperhidrosis FDA indication, changed title, updated to new format.
08/15/05	Revised and Updated: added description, updated when services are covered, dosage/administration, precautions, CPT coding, ICD-9 diagnoses codes that support medical necessity, and references.
01/01/06	CPT code update. Revised codes: 31571, 64613, deleted expired code 90782.
02/15/06	Updated CPT coding: added 64614 chemo denervation of muscle(s), extremity (s), and/or trunk muscle (s) (e.g., for dystonia, cerebral palsy, multiple sclerosis).
05/15/06	Changed descriptor of CPT-4 code 92265 and added CPT-4 code 90772.
10/15/06	Revision consisting of adding CPT code 46505.
11/15/06	Removed ICD-9 codes until reviewed in January 2007.
01/01/07	MCG revised to include Medicare Part D as a program exception.
02/15/07	Annual Review; added indication for incontinence due to detrusor overactivity caused by spinal cord injury inadequately controlled by anticholinergic therapy. Reformatted and updated references.
04/15/07	Revision; consisting of adding CPT-4 codes 95872, 95873 & 95874 to range of codes.
06/15/07	Reformatted guideline.
11/15/07	Review and revision; consisting of rewriting the “Description” section, rewriting the “Dosage and Administration” section, removed Medicare Advantage from “Program Exceptions”, and updated references.
01/01/09	Annual HCPCS coding update: deleted code 90772; added code 96372.

05/15/09	Review and revision; consisting of removing diagnosis of Equines foot, Infantile Cerebral Palsy, Neuromyelitis optica and spasticity with pain and adding drooling associated with Parkinson disease, reformatted guideline and updated references.
10/15/09	Revision; consisting of adding new drug, Dysport™, changing name of MCG, revising description, adding Precautions section and updating references.
01/01/10	Annual HCPCS coding update: added HCPCS code J0586 and revised descriptor for codes 95870, J0585, and J0587.
02/15/10	Review and revision; consisting of adding palmar hyperhidrosis as a covered indication and updating references.
11/15/10	Revision; consisting of adding description of new botulinum toxin and including in the position statement.
02/15/11	Review and revision; consisting of adding updating position statement coding and references.
04/01/11	Revision; consisting of updating codes.
08/05/11	Revision: changes to language around Certificate of Medical Necessity; grammatical changes.
01/01/12	Revision to guideline; consisting of updating codes.
02/15/11	Review and revision to guideline; consisting of updating position statement, precautions, coding and references.
11/15/12	Revision to guideline; consisting of clarifying blepharospasm and hyperhidrosis criteria.
02/15/13	Review and revision to guideline; consisting of reformatting and revising position statement to expand coverage to allow for treatment of essential tremor and gustatory sweating; revised description, dosage/administration, and precautions sections; updated references; added pertinent definitions.
03/15/13	Review and revision to guideline; consisting of revising position statement to include coverage of idiopathic overactive bladder and updating references.
05/15/13	Review and revision to guideline; consisting of adding quantity limit and approval duration.
01/15/14	Revision to guideline; consisting of adding continuation criteria.
02/15/14	Review and revision to guideline; consisting of updating the position statement and references.
09/15/14	Revision to guideline; consisting of revising position statement and updating references.
02/15/15	Review and revision to guideline, consisting of updating references
05/15/15	Revision; updated billing/coding
06/15/15	Revision to guideline, consisting of updating position statement and references.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/15	Revision to guidelines, consisting of updating position statement based on a new FDA-approved indication for Dysport.
01/15/16	Revision to guidelines consisting of updating the position statement.
02/15/16	Revision to guidelines consisting of updating the position statement and references.
05/15/16	Revision to guidelines consisting of clarifying dosage limits in position statement, new FDA-approved indication for Botox, and revision of ICD-10 codes.

10/01/16	Revision: ICD-10 code updates and new FDA-approved indication for Dysport.
12/15/16	Revision: The re-dosing interval was modified from 90 days to 12 weeks with a corresponding authorization duration of 24 weeks
02/15/17	Review and revision to guideline consisting of updating the position statement and references.
07/15/17	Revision to guideline consisting of clarifying the position statement and updating the dosage/administration section.
11/15/17	Revision to guideline consisting of updating the position statement and dosage/administration section with a higher dosage limit for Dysport.
01/15/18	Review and revision to guideline consisting of updating the position statement, program exceptions, dosing/administration, precautions, and references.
07/15/18	Revision to guideline consisting of updating the position statement with an increased maximum dosage limit for Myobloc on continuation of therapy for cervical dystonia.
09/15/18	Revision to guideline consisting of updating the position statement, dosage/administration section, and references based on Xeomin's new FDA-approved indication of chronic sialorrhea in adults.
01/15/19	Review and revision to guideline consisting of updating the description section, position statement and references.
05/15/19	Revision to guideline consisting of updating the description, position statement, and references.
07/15/19	Revision to guideline consisting of updating the position statement, dosage/administration section, and references.
08/15/19	Revision to guideline consisting of updating the dosage/administration section and references.
01/15/20	Review and revision to guideline consisting of updating the position statement, dosage/administration, and references.
04/15/20	Revision to guideline consisting of updating the position statement and dosage/administration section.
09/01/20	Revision to guideline consisting of updating the position statement and dosage/administration section.
01/15/21	Review and revision to guideline consisting of updating the position statement, dosage/administration, and references.
02/15/21	Revision to guideline consisting of updating the position statement and dosage/administration section.
04/15/21	Revision to guideline consisting of updating the position statement, dosage/administration, and references.
05/15/21	Revision to guideline consisting of updating the position statement.
07/15/21	Revision to guideline consisting of updating the dosage/administration section and references.
01/15/22	Review and revision to guideline consisting of updating the position statement and references.
07/15/22	Revision to guideline consisting of updating the "Other" section.

01/15/23	Review and revision to guideline consisting of updating the description section, position statement, and references. Daxxify (daxibotulinumtoxinA-lanm) added as cosmetic use-only botulinum toxin. The separate CGRP receptor antagonists step requirement was moved into the single step requirement of at least one prophylactic migraine agent.