Medical Drug Clinical Criteria

Subject:	Botulinum Toxin		
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Overview

This document addresses the use of botulinum toxin agents: Daxxify (daxibotulinumtoxinA-lanm), 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; severe 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; neurogenic detrusor overactivity in children 5 years of age and older who have an inadequate response to or are intolerant of an anticholinergic medication; prophylaxis of chronic migraine headaches in adults; spasticity in individuals 2 years of age and older; 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 in adults and for the treatment of chronic sialorrhea in adults.

The FDA approved label for Dysport specifies that it is indicated for the treatment of cervical dystonia in adults; spasticity in adults and 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 received FDA approval for the treatment of cervical dystonia in adults; blepharospasm in adults; upper limb spasticity in adults; excessive salivation (chronic sialorrhea) in individuals 2 years of age and older; upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy; and the temporary improvement in the appearance of moderate to severe frown lines between the eyebrows (glabellar lines) in adults.

Daxxify received FDA approval for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults and for the treatment of cervical dystonia 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, carpel 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.

Botulinum toxin 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, including but not limited to internal anal sphincter achalasia with abnormal rectoanal inhibitory reflex (RAIR) or internal anal sphincter hypertonicity shown by anorectal manometry (ARM) (Irani 2008); **OR**
   C. Anal fissures; **OR**
   D. Significant drooling in individuals who are unable to tolerate anticholinergic therapy (ex. glycopyrrolate, 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

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. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease;

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 to a 2 month trial at target or usual effective dose 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, AHS 2021):~~
~~A. One of the following antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine; **OR**~~
~~B. One of the following beta blockers: atenolol, metoprolol, nadolol, nebivolol, propranolol, timolol (oral); **OR**~~
~~C. The following calcium channel blocker: verapamil; **OR**~~
~~D. One of the following antiepileptic agents: divalproex sodium, gabapentin, topiramate, valproate sodium;~~

AND
~~XIV.~~XIII. If individual is also currently using a calcitonin gene-related peptide (CGRP) agent for chronic migraine prophylaxis and is going to be using CGRP and botulinum toxin together (i.e., not switching from one agent to another), the following must apply:
A. Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with CGRP use; **AND**
B. Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention;

Initial approval duration for chronic migraine headaches: 6 months

OR
~~XV.~~XIV. Individual has a diagnosis of chronic migraine headaches; **AND**
~~XVI.~~XV. Individual is requesting continued treatment; **AND**
~~XVII.~~XVI. 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 including any of the following (AHS 2021):
1. 50% reduction in frequency of days with headache or migraine; **OR**
2. Significant decrease in attack duration; **OR**
3. Significant decrease in attack severity; **OR**
4. Improved response to acute treatment; **OR**
5. Reduction in migraine-related disability and improvements in functioning in important areas of life; **OR**
6. Improvements in health related quality of life and reduction in psychological stress due to migraine;

AND
C. If individual is using concurrently with a CGRP agent for migraine prophylaxis, the following must apply:
1. Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or the CGRP agent);

Renewal approval duration for chronic migraine headaches: 1 year

OR
~~XVIII.~~XVII. Individual has a diagnosis of primary hyperhidrosis; **AND**
~~XIX.~~XVIII. 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.~~XIX. Individual has one of the following:
A. Presence of medical complications or skin maceration with secondary infection; **OR**
B. Significant functional impairment (including but not limited to social, occupational, physical or emotional impairment), as defined by frequent interference with daily activities;

OR
~~XXI.~~XX. Individual has a diagnosis of secondary hyperhidrosis; **AND**

~~XXII.~~XXI. Condition is related to surgical complications; **AND**
~~XXIII.~~XXII. Individual has one of the following:
A. Presence of medical complications or skin maceration with secondary infection; **OR**
B. Significant functional impairment (including but not limited to social, occupational, physical or emotional impairment), as defined by frequent interference with daily activities.

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 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**
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.

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 [cumulative for all indications treated] of: • 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 (including neurogenic detrusor overactivity in children age 5 and older): 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 8 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 lower limb 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: 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
Daxxify (daxibotulinumtoxinA-lanm) 50 unit, 100 unit vial	**Cervical Dystonia:** 125 to 250 units as a divided dose among affected muscles as frequently as every 3 months	250 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; as frequently as every 16 weeks	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; as frequently as every 12 weeks	1000 units
	Blepharospasm: 120 units per eye as frequently as every 12 weeks (DP)	300 units
	Hemifacial spasm: 220 units as frequently as every 12 weeks (DP)	300 units
Myobloc (rimabotulinumtoxinB) 2500 unit, 5000 unit, 10000 unit vial	**Cervical dystonia:** Initial dose of 2,500 – 5,000 units divided among effected muscles as frequently as every 12 weeks; subsequent doses should be based on individual response to treatment, up to 10,000 units as frequently as every 12 weeks	10,000 units
	Chronic sialorrhea in adults: 1,500 – 3.500 units (500 units – 1,500 units per parotid gland and 250 units per submandibular gland) as frequently as every 12 weeks	5000 units
	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) as frequently as every 12 weeks	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 (25^{th} to 75^{th} 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]
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit [Daxxify]
S2340	Chemodenervation of abductor muscle(s) of vocal cord
S2341	Chemodenervation 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)
K59.89	Other specified functional intestinal disorders
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 7th character 'S']
S14.101S-S14.159S	Other and unspecified injury of cervical spinal cord [code range, includes codes within this range with 7th character 'S']
S24.101S-S24.159S	Other and unspecified injury of thoracic spinal cord [code range, includes codes within this range with 7th character 'S']
S34.101S-S34.139S	Other and unspecified injury of lumbar and sacral spinal cord [code range, includes codes within this range with 7th character 'S']

Document History

Revised: 06/10/2024
Document History:

- 06/10/2024 – Annual Review: Remove step through migraine prophylaxis agents; move Daxxify to potential preferred based on clinical designation. Coding Reviewed: No changes.
- 11/17/2023 – Select Review: Add new agent Daxxify to clinical criteria and quantity limits. Coding Reviewed: Added HCPCS J3590 for Daxxify. Effective 1/1/2024 Added HCPCS C9160 for Daxxify. Effective 4/1/2024 Added HCPCS J0589. Removed HCPCS J3590, C9160.
- 6/12/2023 – Select Review: Clarified individual has to have either presence of medical complications or skin maceration with secondary infection or significant functional impairment for diagnosis of secondary hyperhidrosis. Coding Reviewed: No changes.5/19/2023 – Annual Review: Remove confirmation language; update Botox quantity limit note to clarify max dose is cumulative for all indications treated; update Dysport, Myobloc, and Xeomin quantity limit with frequency for certain indications based on label and clinical trials; consistency wording change for migraine combination use; wording and formatting updates. Coding Reviewed: No changes.
- 5/20/2022 – Annual Review: Update chronic migraine criteria to include combination use with CGRP agents within specific initial and continuation sections for clarity; update hyperhidrosis to specify requirements around functional impairment; update quantity limit for axillary hyperhidrosis to every 8 weeks based on clinical trial within the label; wording and formatting updates. Coding Reviewed: No changes.
- 5/21/2021 – Annual Review: Updated achalasia indication to clarify it includes internal anal sphincter achalasia; Updated migraine indication as follows: require 2 month trial of agents for migraine prophylaxis, added nortriptyline and duloxetine as allowable agents for migraine prophylaxis (AHS 2019), removed may not be approved criteria for concurrent use with prophylactic CGRP agents, updated criteria to include specific examples of clinical benefit, added allowance for concurrent therapy with prophylactic CGRP agents for initial and continued concurrent therapy; Removed may not be approved criteria for prior treatment failure of botulinum toxin for any condition; updated FDA and off-label indication chart based on new labeled indications and updated compendia off-label indications; updated quantity limit charts for new indications. Coding Reviewed: Added ICD-10-CM K59.89.

- 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.

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