

## Medical Policy: NEUROTOXINS (Botox<sup>®</sup>, Daxxify, Dysport<sup>™</sup>, Myobloc<sup>®</sup> and Xeomin<sup>®</sup>)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.01	January 18, 2024	

### Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG<sup>™</sup> Care Guidelines, to assist us in administering health benefits. The MCG<sup>™</sup> Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Neurotoxins (referred to in this guideline collectively as musculoskeletal agents) are produced by Clostridium botulinum. There are seven known serotypes; out of these, only A and B are approved medicinally.

Musculoskeletal agents produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings, which results in the chemical denervation of muscle causing local paresis or paralysis.

Selected muscles such as these can be treated — overactive skeletal muscles (e.g. hemifacial spasm, dystonia, and spasticity), smooth muscles (e.g. detrusor overactivity and achalasia), glands (e.g. sialorrhea and hyperhidrosis); others are currently being investigated (see also [Off-Label Use of FDA-Approved Drug and Biologics Guidelines](#)).

There are four commercially available products in the United States; each with distinct pharmacological and clinical profiles, as well as dosing patterns.

Agent	Prescribing Information
A. Botox <sup>®</sup> (onabotulinumtoxinA)	<a href="http://www.allergan.com/assets/pdf/botox_pi.pdf">http://www.allergan.com/assets/pdf/botox_pi.pdf</a>
B. Dysport <sup>™</sup> (abobotulinumtoxinA)	<a href="http://www.galdermausa.com/IFU/Dysport_IFU.pdf?_ga=1.205661723.920858028.1472140306">http://www.galdermausa.com/IFU/Dysport_IFU.pdf?_ga=1.205661723.920858028.1472140306</a>

C. Myobloc® (rimabotulinumtoxinB)	<a href="https://myobloc.com/files/MYOBLOC_PI.pdf">https://myobloc.com/files/MYOBLOC_PI.pdf</a>
D. Xeomin® (incobotulinumtoxinA)	<a href="http://www.xeominaesthetic.com/wp-content/uploads/XEOMIN-Prescribing-Information.pdf">http://www.xeominaesthetic.com/wp-content/uploads/XEOMIN-Prescribing-Information.pdf</a>
E. Daxxify (daxibotulinumtoxinA-lanm)	<a href="https://www.daxxify.com/">https://www.daxxify.com/</a>

## Guideline

Members ≥ 18 years of age (or unless otherwise specified) are eligible for coverage of musculoskeletal agents per the criteria below.

### A. Botox — any:

1. Blepharospasms (≥ 12 years of age)
2. Cervical dystonia (≥ 16 years of age) to reduce the severity of abnormal head position and neck pain.
3. Strabismus in members (≥ 12 years of age)
4. Lower limb spasticity, Excluding Spasticity Caused by Cerebral Palsy (≥ 2 years of age)
5. Upper limb spasticity (≥ 2 years of age)
6. Severe palmar hyperhidrosis — both:
  - a. Failure of topical agents and pharmacotherapy (unless contraindicated)
  - b. History of medical complications (e.g., skin infections/functional impairments) or significant impact to activities of daily living (directly attributable to the condition).
7. Severe primary axillary hyperhidrosis — both:
  - a. Failure of topical agents and pharmacotherapy (unless contraindicated)
  - b. History of medical complications (e.g., skin infections/functional impairments) or significant impact to activities of daily living (directly attributable to the condition).
8. Chronic daily headache (migraine or tension-type) — all:
  - a. Patient has clinically diagnosed migraine as defined as at least 8 migraine days per month (or 15 headache days); **AND**
  - b. Patient has prior usage of at least **TWO** standard prophylactic pharmacologic therapies, each from a different pharmacologic class, used to prevent migraines or reduce migraine frequency including:
    - i. Angiotensin receptor blockers;
    - ii. Angiotensin Converting Enzyme Inhibitors;
    - iii. Beta-blockers (i.e. propranolol, metoprolol, atenolol);
    - iv. Calcium Channel blockers (i.e. verapamil);
    - v. Anti-epileptics (i.e. as topiramate or divalproex sodium);
    - vi. Antidepressants (venlafaxine OR a tricyclic antidepressant such as amitriptyline or nortriptyline); **AND**
  - c. The patient has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; **OR**
  - d. The patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; **OR**
  - e. Patient meets **BOTH** of the following (i. and ii.):
    - i. Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy; **AND**

- ii. Patient has experienced adverse event(s) severe enough to warrant discontinuation of another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber
  - f. **FOR MEDICAID PATIENTS ONLY:** failure of two oral agents FDA-approved or compendia-supported for prevention of migraine ONLY
- 9. Esophageal achalasia — any:
  - a. High risk of complication from pneumatic dilation or surgical myotomy
  - b. Failed pneumatic dilation or surgical myotomy
  - c. Perforation attributable to pneumatic dilation
  - d. Presence of epiphrenic diverticulum or hiatal hernia
  - e. Presence of esophageal varices
- 10. Oromandibular dystonia of isolated nature
- 11. Laryngeal dystonia
- 12. Cerebral palsy with concurrent equinus gait
- 13. Sialorrhea — failure of oral therapy in the presence of any:
  - a. Severe developmental delays
  - b. Cerebral palsy
  - c. Parkinson’s disease
  - d. ALS secondary to other neurological disorders
  - e. **FOR MEDICAID PATIENTS ONLY:** failure of glycopyrrolate only, this excludes patients with Parkinson’s disease and other neurodegenerative diseases
- 14. Urinary incontinence due to detrusor overactivity — failed or intolerant to anticholinergic medication
  - a. **FOR MEDICAID PATIENTS ONLY:** failure of an antimuscarinic agent **OR** beta-3-adrenoceptor agonist only
- 15. 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
  - a. **FOR MEDICAID PATIENTS ONLY:** failure of an antimuscarinic agent **OR** beta-3-adrenoceptor agonist
- 16. Focal upper limb dystonia with either pain or functional impairment
- 17. Idiopathic (primary or genetic) torsion and symptomatic (acquired) torsion dystonia
- 18. Hereditary spastic paraplegia
- 19. Infantile cerebral palsy
- 20. Spasticity due to multiple sclerosis
- 21. Neuromyelitis optica
- 22. Schilder’s disease
- 23. Spastic hemiplegia
- 24. Chronic anal fissure — failed conventional therapy
- 25. Idiopathic transverse myelitis
- 26. Quadriplegia
- 27. Paraplegia
- 28. Diplegia of upper limbs
- 29. Monoplegia
- 30. Spastic ENT/ectropion
- 31. Hemiplegia

32. Hemifacial spasm
33. Other paralytic syndromes
34. Pediatric Spasticity
35. Temporomandibular Joint disorder – all of the following criteria have to be met:
  - a. Member has diagnosis of Temporomandibular Disorder (TMD); **AND**
  - b. Documentation has been provided with detailed description of clinical manifestations (e.g. facial pain, ear discomfort or dysfunction, headache, TMJ discomfort or dysfunction, etc); **AND**
  - c. Member has a chronic condition with persistent functional limitations despite  $\geq 3$  months of nonsurgical management.
36. Neurogenic detrusor overactivity- **FOR MEDICAID PATIENTS ONLY**: failure of an antimuscarinic agent; this excludes patients with multiple sclerosis (MS) or spinal cord injury

**B. Dysport** —  $\geq 18$  years of age and either:

1. Cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients
2. Blepharospasm
3. Spasticity in adults 18+
4. Hemifacial spasm
5. Lower limb spasticity in pediatric patients ( $\geq 2$  years of age)
6. Upper Limb Spasticity in Pediatric Patients, Excluding Spasticity Caused by Cerebral Palsy ( $\geq 2$  years of age)

**C. Myobloc** — any:

1. Cervical dystonia (in adults) to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
2. Bladder muscle dysfunction
3. Excessive salivation

**D. Xeomin**

1.  $\geq 18$  years of age and either:
  - a. Cervical dystonia (in adults) to decrease the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients
  - b. Blepharospasm
  - c. Upper limb spasticity
  - d. Excessive salivation, chronic
2.  $\geq 2$  years of age:
  - a. Upper limb spasticity excluding spasticity caused by cerebral palsy

**E. Daxxify**

1.  $\geq 18$  years of age and
  - a. Cervical dystonia (in adults) to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

## Documentation

The following elements must be made available to the plan upon request:

1. Dosage and frequency
2. Support of clinical effectiveness/medical necessity
3. Support of medical necessity for electromyography procedures to determine injection site location
4. Specification of injection site(s)
5. Post-session results and treatment response.

---

## Utilization/Limitations

1. Electromyography or muscle stimulation, rather than site pain or tenderness, to determine injection site(s) may be necessary, especially for spastic conditions of the face, neck, and upper extremity.
2. The plan will allow coverage for one dose per affected site, in accordance with FDA-approved dosing limitations.
3. A site is defined as one eye (including all muscles surrounding the eye including both upper and lower lids); one side of the face; the neck; or the trunk and all limbs and their associated girdle muscles.
4. It is generally not considered medically necessary to give musculoskeletal agents more frequently than every 90 days for spastic or excess muscular contraction conditions. With a positive response, the effect generally lasts for 3 months, at which time repeat injections to control the spastic or excessive muscular condition may be warranted.
5. Failure of two definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further coverage of the serotype used in the treatment for a period of one year after the second session. It may be reasonable, however, to attempt treatment with a different serotype.
6. For certain spastic conditions (e.g., cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis), coverage will be limited to those conditions listed in the diagnostic coding section. All other uses in the treatment of other types of spasm (including smooth muscle types) will be considered investigational and therefore not covered (except where included in the list of covered indications in the coding section).
7. For blepharospasm, if the upper and lower lid of the same eye or adjacent facial muscles or brow is injected with an agent at the same surgery, the procedure is considered to be unilateral. Procedures will only be considered bilateral when both eyes or both sides of the face are injected.

---

## Exclusions

1. Infection at the proposed injection site.
2. Injections exceeding the frequencies depicted in the Utilization section are not considered medically necessary.
3. Agents used for cosmetic purposes (e.g., wrinkles) are not considered medically necessary
4. Treatment of the following conditions is not considered medically necessary, as there is insufficient evidence to support effectiveness:
  - a. Spastic conditions not listed in the ICD-9 table.
  - b. Biliary dyskinesia
  - c. Irritable bowel
  - d. Pain conditions not associated with spasticity/dystonia to include myofascial pain and fibromyalgia.
  - e. Plantar hyperhidrosis
  - f. Wrinkles

## Applicable Procedure Codes

Code	Description
31513	Laryngoscopy, indirect; with vocal cord injection
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic;

31571	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope
43201	Esophagoscopy, rigid or flexible, transoral; with directed submucosal injection(s), any substance
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
46505	Chemodenervation of internal anal sphincter
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder New code effective date 01/01/2013
53899	Unlisted procedure, urinary system
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., for cervical dystonia, spasmodic torticollis) (new code effective 01/01/2014)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed (new code effective 01/01/2014)
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (list separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscle(s)
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day
67345	Chemodenervation of extraocular muscle
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
J3590	Unclassified biologic

## Applicable NDCs

Code	Description
00023-1145-xx	BOTOX 100UNIT Solution Reconstituted
00023-3921-02	BOTOX 200UNIT Solution Reconstituted
10454-0710-10	MYOBLOC 2500UNIT/0.5ML Solution
10454-0711-10	MYOBLOC 5000UNIT/ML Solution
10454-0712-10	MYOBLOC 10000UNIT/2ML Solution
00299-5962-30	DYSPORE 300UNIT Solution Reconstituted
15054-0530-06	DYSPORE 300UNIT Solution Reconstituted
15054-0500-01	DYSPORE 500UNIT Solution Reconstituted
00259-1605-01	XEOMIN 50UNIT Solution Reconstituted
46783-0161-01	XEOMIN 50UNIT Solution Reconstituted
00259-1610-01	XEOMIN 100UNIT Solution Reconstituted
46783-0160-01	XEOMIN 100UNIT Solution Reconstituted
00259-1620-10	XEOMIN 200UNIT Solution Reconstituted
00259-1620-01	XEOMIN 200UNIT Solution Reconstituted

## ICD-10 Diagnoses

Code	Description
G04.1	Tropical spastic paraplegia
G11.4	Hereditary spastic paraplegia
G24.09	Other drug induced dystonia
G24.1	Genetic torsion dystonia
G24.2	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
G35	Multiple sclerosis
G36.0	Neuromyelitis optica [Devic]
G36.1	Acute and subacute hemorrhagic leukoencephalitis [Hurst]
G36.8	Other specified acute disseminated demyelination
G36.9	Acute disseminated demyelination, unspecified
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
G37.4	Subacute necrotizing myelitis 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
G43.019	Migraine without aura, intractable, without status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.901	Migraine, unspecified, not intractable, with status migrainosus
G43.909	Migraine, unspecified, not intractable, without status migrainosus
G43.911	Migraine, unspecified, intractable, with status migrainosus
G43.919	Migraine, unspecified, intractable, without status migrainosus
G44.221	Chronic tension-type headache, intractable
G44.229	Chronic tension-type headache, not intractable
G51.2	Melkersson's syndrome
G51.3	Clonic hemifacial spasm
G51.4	Facial myokymia
G51.8	Other disorders of facial nerve
G80.0	Spastic quadriplegic cerebral palsy

G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.3	Athetoid cerebral palsy
G80.4	Ataxic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
G81.10	Spastic hemiplegia affecting unspecified side
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G81.13	Spastic hemiplegia affecting right nondominant side
G81.14	Spastic hemiplegia affecting left nondominant side
G82.20	Paraplegia, unspecified
G82.21	Paraplegia, complete
G82.22	Paraplegia, incomplete
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G82.54	Quadriplegia, C5-C7 incomplete
G83.0	Diplegia of upper limbs
G83.10	Monoplegia of lower limb affecting unspecified side
G83.11	Monoplegia of lower limb affecting right dominant side
G83.12	Monoplegia of lower limb affecting left dominant side
G83.13	Monoplegia of lower limb affecting right nondominant side
G83.14	Monoplegia of lower limb affecting left nondominant side
G83.20	Monoplegia of upper limb affecting unspecified side
G83.21	Monoplegia of upper limb affecting right dominant side
G83.22	Monoplegia of upper limb affecting left dominant side
G83.23	Monoplegia of upper limb affecting right nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
H02.041	Spastic entropion of right upper eyelid
H02.042	Spastic entropion of right lower eyelid
H02.043	Spastic entropion of right eye, unspecified eyelid
H02.044	Spastic entropion of left upper eyelid
H02.045	Spastic entropion of left lower eyelid
H02.046	Spastic entropion of left eye, unspecified eyelid
H02.049	Spastic entropion of unspecified eye, unspecified eyelid
H02.141	Spastic ectropion of right upper eyelid
H02.142	Spastic ectropion of right lower eyelid
H02.143	Spastic ectropion of right eye, unspecified eyelid
H02.144	Spastic ectropion of left upper eyelid
H02.145	Spastic ectropion of left lower eyelid
H02.146	Spastic ectropion of left eye, unspecified eyelid
H02.149	Spastic ectropion of unspecified eye, unspecified eyelid
H49.00	Third [oculomotor] nerve palsy, unspecified eye
H49.01	Third [oculomotor] nerve palsy, right eye



H49.02	Third [oculomotor] nerve palsy, left eye
H49.03	Third [oculomotor] nerve palsy, bilateral
H49.10	Fourth [trochlear] nerve palsy, unspecified eye
H49.11	Fourth [trochlear] nerve palsy, right eye
H49.12	Fourth [trochlear] nerve palsy, left eye
H49.13	Fourth [trochlear] nerve palsy, bilateral
H49.20	Sixth [abducent] nerve palsy, unspecified eye
H49.21	Sixth [abducent] nerve palsy, right eye
H49.22	Sixth [abducent] nerve palsy, left eye
H49.23	Sixth [abducent] nerve palsy, bilateral
H49.30	Total (external) ophthalmoplegia, unspecified eye
H49.31	Total (external) ophthalmoplegia, right eye
H49.32	Total (external) ophthalmoplegia, left eye
H49.33	Total (external) ophthalmoplegia, bilateral
H49.40	Progressive external ophthalmoplegia, unspecified eye
H49.41	Progressive external ophthalmoplegia, right eye
H49.42	Progressive external ophthalmoplegia, left eye
H49.43	Progressive external ophthalmoplegia, bilateral
H49.881	Other paralytic strabismus, right eye
H49.882	Other paralytic strabismus, left eye
H49.883	Other paralytic strabismus, bilateral
H49.889	Other paralytic strabismus, unspecified eye
H49.9	Unspecified paralytic strabismus
H50.00	Unspecified esotropia
H50.011	Monocular esotropia, right eye
H50.012	Monocular esotropia, left eye
H50.021	Monocular esotropia with A pattern, right eye
H50.022	Monocular esotropia with A pattern, left eye
H50.031	Monocular esotropia with V pattern, right eye
H50.032	Monocular esotropia with V pattern, left eye
H50.041	Monocular esotropia with other noncomitancies, right eye
H50.042	Monocular esotropia with other noncomitancies, left eye
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	Monocular exotropia, right eye
H50.112	Monocular exotropia, left eye
H50.121	Monocular exotropia with A pattern, right eye
H50.122	Monocular exotropia with A pattern, left eye
H50.131	Monocular exotropia with V pattern, right eye
H50.132	Monocular exotropia with V pattern, left eye
H50.141	Monocular exotropia with other noncomitancies, right eye
H50.142	Monocular exotropia with other noncomitancies, left eye
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	Vertical strabismus, right eye
H50.22	Vertical strabismus, left eye
H50.30	Unspecified intermittent heterotropia
H50.311	Intermittent monocular esotropia, right eye
H50.312	Intermittent monocular esotropia, left eye
H50.32	Intermittent alternating esotropia
H50.331	Intermittent monocular exotropia, right eye
H50.332	Intermittent monocular exotropia, left eye
H50.34	Intermittent alternating exotropia
H50.40	Unspecified heterotropia
H50.411	Cyclotropia, right eye
H50.412	Cyclotropia, left eye
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	Brown's sheath syndrome, right eye
H50.612	Brown's sheath syndrome, left eye
H50.69	Other mechanical strabismus
H50.811	Duane's syndrome, right eye
H50.812	Duane's syndrome, left eye
H50.89	Other specified strabismus
H50.9	Unspecified strabismus
H51.0	Palsy (spasm) of conjugate gaze
H51.11	Convergence insufficiency
H51.12	Convergence excess
H51.20	Internuclear ophthalmoplegia, unspecified eye
H51.21	Internuclear ophthalmoplegia, right eye
H51.22	Internuclear ophthalmoplegia, left eye
H51.23	Internuclear ophthalmoplegia, bilateral
H51.8	Other specified disorders of binocular movement
H51.9	Unspecified disorder of binocular movement
I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side

I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.041	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.042	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.043	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.044	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.061	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.062	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.063	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.064	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.065	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage, bilateral
I69.069	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.161	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.162	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.163	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.164	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.165	Other paralytic syndrome following nontraumatic intracerebral hemorrhage, bilateral
I69.169	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side

I69.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.261	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.262	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.263	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.264	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.265	Other paralytic syndrome following other nontraumatic intracranial hemorrhage, bilateral
I69.269	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.339	Monoplegia of upper limb following cerebral infarction affecting unspecified side
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
I69.361	Other paralytic syndrome following cerebral infarction affecting right dominant side
I69.362	Other paralytic syndrome following cerebral infarction affecting left dominant side
I69.363	Other paralytic syndrome following cerebral infarction affecting right non-dominant side
I69.364	Other paralytic syndrome following cerebral infarction affecting left non-dominant side
I69.365	Other paralytic syndrome following cerebral infarction, bilateral
I69.369	Other paralytic syndrome following cerebral infarction affecting unspecified side
I69.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
I69.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
I69.833	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side
I69.834	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side
I69.839	Monoplegia of upper limb following other cerebrovascular disease affecting unspecified side
I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
I69.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side
I69.853	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side
I69.854	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side
I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side
I69.861	Other paralytic syndrome following other cerebrovascular disease affecting right dominant side
I69.862	Other paralytic syndrome following other cerebrovascular disease affecting left dominant side
I69.863	Other paralytic syndrome following other cerebrovascular disease affecting right non-dominant side

I69.864	Other paralytic syndrome following other cerebrovascular disease affecting left non-dominant side
I69.865	Other paralytic syndrome following other cerebrovascular disease, bilateral
I69.869	Other paralytic syndrome following other cerebrovascular disease affecting unspecified side
I69.931	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side
I69.932	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
I69.933	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.934	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side
I69.951	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side
I69.952	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side
I69.953	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side
I69.954	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side
I69.959	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side
I69.961	Other paralytic syndrome following unspecified cerebrovascular disease affecting right dominant side
I69.962	Other paralytic syndrome following unspecified cerebrovascular disease affecting left dominant side
I69.963	Other paralytic syndrome following unspecified cerebrovascular disease affecting right non-dominant side
I69.964	Other paralytic syndrome following unspecified cerebrovascular disease affecting left non-dominant side
I69.965	Other paralytic syndrome following unspecified cerebrovascular disease, bilateral
I69.969	Other paralytic syndrome following unspecified cerebrovascular disease affecting unspecified side
J38.5	Laryngeal spasm
K11.7	Disturbances of salivary secretion
K22.0	Achalasia of cardia
K60.0	Acute anal fissure
K60.1	Chronic anal fissure
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
M26.6	Temporomandibular joint disorders
M26.60	Temporomandibular joint disorder, unspecified
M43.6	Torticollis
M62.40	Contracture of muscle, unspecified site
M62.411	Contracture of muscle, right shoulder
M62.412	Contracture of muscle, left shoulder
M62.419	Contracture of muscle, unspecified shoulder
M62.421	Contracture of muscle, right upper arm
M62.422	Contracture of muscle, left upper arm
M62.429	Contracture of muscle, unspecified upper arm
M62.431	Contracture of muscle, right forearm
M62.432	Contracture of muscle, left forearm
M62.439	Contracture of muscle, unspecified forearm
M62.441	Contracture of muscle, right hand
M62.442	Contracture of muscle, left hand
M62.449	Contracture of muscle, unspecified hand

M62.451	Contracture of muscle, right thigh
M62.452	Contracture of muscle, left thigh
M62.459	Contracture of muscle, unspecified thigh
M62.461	Contracture of muscle, right lower leg
M62.462	Contracture of muscle, left lower leg
M62.469	Contracture of muscle, unspecified lower leg
M62.471	Contracture of muscle, right ankle and foot
M62.472	Contracture of muscle, left ankle and foot
M62.479	Contracture of muscle, unspecified ankle and foot
M62.48	Contracture of muscle, other site
M62.49	Contracture of muscle, multiple sites
M62.830	Muscle spasm of back
M62.831	Muscle spasm of calf
M62.838	Other muscle spasm
N31.0	Uninhibited neuropathic bladder, not elsewhere classified
N31.1	Reflex neuropathic bladder, not elsewhere classified
N31.8	Other neuromuscular dysfunction of bladder
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder
N36.44	Muscular disorders of urethra
N39.3	Stress incontinence (female) (male)
N39.41	Urge incontinence
N39.42	Incontinence without sensory awareness
N39.43	Post-void dribbling
N39.44	Nocturnal enuresis
N39.45	Continuous leakage
N39.46	Mixed incontinence
N39.490	Overflow incontinence
N39.498	Other specified urinary incontinence
R32	Unspecified urinary incontinence
R35.0	Frequency of micturition
R39.15	Urgency of urination

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/18/2024	Update: Initial Criteria: Botox: Chronic daily headache (migraine or tension-type) — all: Clarified the following 3 statements “Frequency ≥ 15 days a month, Duration ≥ 4 hours for ≥ 3-month period, Failure of ≥ 2-month trial of oral pharmacotherapy (e.g., antidepressants, anti-epileptics, angiotensin converting enzyme inhibitors, beta/calcium channel blockers, etc.) unless contraindicated “ to read: “Patient has clinically diagnosed migraine as defined as at least 8 migraine days per month (or 15 headache days); AND Patient has prior usage of at least TWO standard prophylactic pharmacologic therapies, each from a different pharmacologic class, used to prevent migraines or reduce migraine frequency including:Angiotensin receptor blockers; Angiotensin Converting Enzyme Inhibitors; Beta-blockers (i.e. propranolol, metoprolol, atenolol); Calcium Channel blockers (i.e. verapamil); Anti-epileptics

		(i.e. as topiramate or divalproex sodium); Antidepressants (venlafaxine OR a tricyclic antidepressant such as amitriptyline or nortriptyline); AND The patient has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; OR The patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; OR Patient meets BOTH of the following (i. <u>and</u> ii.): Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy; AND Patient has experienced adverse event(s) severe enough to warrant discontinuation of another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber”												
EmblemHealth & ConnectiCare	10/23/2023	Addition of Daxxify to policy with the following criteria; 1. ≥ 18 years of age and Cervical dystonia (in adults) to reduce the severity of abnormal head position and neck pain associated with cervical dystonia Addition of NDC for Daxxify 72960-0112-01												
EmblemHealth & ConnectiCare	6/1/2023	Annual Review: no criteria changes												
EmblemHealth & ConnectiCare	11/17/2022	Added <b>For Medicaid Patients only</b> Update- <b>ST Requirements</b>												
		<table border="1"> <thead> <tr> <th>Indication</th> <th>ST</th> </tr> </thead> <tbody> <tr> <td>Chronic sialorrhea*</td> <td>Glycopyrrolate</td> </tr> <tr> <td>Headache prevention in patients with chronic migraine</td> <td>Two oral agents FDA-approved or compendia-supported for prevention of migraine</td> </tr> <tr> <td>Overactive bladder</td> <td>Antimuscarinic agent or beta-3-adrenoceptor agonist</td> </tr> <tr> <td>Neurogenic detrusor overactivity** (added indication)</td> <td>Antimuscarinic agent</td> </tr> <tr> <td>Urinary incontinence due to detrusor overactivity</td> <td>Antimuscarinic agent or beta-3-adrenoceptor agonist</td> </tr> </tbody> </table>	Indication	ST	Chronic sialorrhea*	Glycopyrrolate	Headache prevention in patients with chronic migraine	Two oral agents FDA-approved or compendia-supported for prevention of migraine	Overactive bladder	Antimuscarinic agent or beta-3-adrenoceptor agonist	Neurogenic detrusor overactivity** (added indication)	Antimuscarinic agent	Urinary incontinence due to detrusor overactivity	Antimuscarinic agent or beta-3-adrenoceptor agonist
Indication	ST													
Chronic sialorrhea*	Glycopyrrolate													
Headache prevention in patients with chronic migraine	Two oral agents FDA-approved or compendia-supported for prevention of migraine													
Overactive bladder	Antimuscarinic agent or beta-3-adrenoceptor agonist													
Neurogenic detrusor overactivity** (added indication)	Antimuscarinic agent													
Urinary incontinence due to detrusor overactivity	Antimuscarinic agent or beta-3-adrenoceptor agonist													
		*Excludes patients with Parkinson's disease and other neurodegenerative diseases. **Excludes patients with multiple sclerosis (MS) or spinal cord injury.												
EmblemHealth & ConnectiCare	09/13/2022	Transferred policy to new template												
EmblemHealth & ConnectiCare	12/16/2020	Clarified coverage:” The plan will allow coverage for one dose per affected site, in accordance with FDA-approved dosing limitations.”												
EmblemHealth & ConnectiCare	11/11/2020	Added Temporomandibular Joint disorder; added pertinent codes: M26.6, M26.60												
EmblemHealth & ConnectiCare	08/27/2020	Added the following indication to Xeomin per FDA Label: Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy												

EmblemHealth & ConnectiCare	04/14/2020	Added the following indication to Dysport per FDA Label: Upper Limb Spasticity in Pediatric Patients, Excluding Spasticity Caused by Cerebral Palsy (≥ 2 years of age)  Updated age and indication for Botox per FDA Label: Lower limb spasticity, Excluding Spasticity Caused by Cerebral Palsy (≥ 2 years of age)
EmblemHealth & ConnectiCare	01/23/2020	Under Guidelines, Dysport, REMOVED – glabellar lines for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age  Under Guidelines, Xeomin, REMOVED- glabellar lines for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity.
EmblemHealth & ConnectiCare	09/30/2019	-Updated age indications under Guidelines, section A. Botox for lower limb spasticity and upper limb spasticity -Under Guidelines, Dysport, added line 2 – Glabellar lines for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age, Dysport, #4. Spasticity, added 18+. -In Guidelines, under Xeomin, added excessive salivation, chronic, glabellar lines for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity. -Under Exclusions, added Infection at the proposed injection site - Removed Related Medical Guideline section - Removed link to Cosmetic Surgery Procedures Added indication for Botox – Pediatric Spasticity
EmblemHealth & ConnectiCare	11/11/2016	Added presence of ALS secondary to other neurological disorders to Sialorrhea indication criteria for Botox Added criteria for palmar hyperhidrosis
EmblemHealth & ConnectiCare	8/24/2016	Added upper limb spasticity to Xeomin
EmblemHealth & ConnectiCare	8/12/2016	Added lower limb spasticity in pediatric patients (> 2 years of age) to Dysport criteria
EmblemHealth & ConnectiCare	3/2/2016	The following paragraph (in the “Utilization/Limitations” section pertaining to spasticity) has been corrected to add “upper extremity” – Electromyography or muscle stimulation, rather than site pain or tenderness, to determine injection site(s) for Botulinum toxin may be necessary, especially for spastic conditions of the face, neck, and upper extremity
EmblemHealth & ConnectiCare	1/21/2016	Added lower limb spasticity as covered indication for Botox

## References

1. Botox [package insert]. Irvine, CA: Allergan; September 2019.
2. Dysport [package insert]. Scottsdale, AZ: Medici’s Pharmaceutical Corporation; September 2019.



3. Myobloc [package insert]. San Francisco, CA: Solstice Neurosciences, Inc; September 2019.
4. Xeomin (incobotulinumtoxinA) package insert. Greensboro, NC: Merz Pharmaceuticals, LLC; September 2019.
5. Freund B, Schwartz M, & Symington JM: The use of botulinum toxin for the treatment of temporomandibular disorders: preliminary findings. J Oral Maxillofac Surg 1999; 57(8):916-920.
6. IBM Micromedex. OnabotulinumToxinA. www.micromedexsolutions.com. Accessed November 2020.
7. NGS Medicare Local Coverage Determination (LCD) for Botulinum Toxins (L26841). September 2019. Accessed September 2019.  
[https://www.cms.gov/medicare-coverage-database/license/cpt-license.aspx?from=~/overview-and-quick-search.aspx&npage=/medicare-coverage-database/details/lcd-details.aspx&LCDId=26841&ContrId=300&ver=93&ContrVer=1&CtrctrSelected=300\\*1&Ctrctr=300&name=National+Government+Services%2c+Inc.+\(National+Government+Services%2c+Inc.+\(13202%2c+A+and+B+and+HHH+MA](https://www.cms.gov/medicare-coverage-database/license/cpt-license.aspx?from=~/overview-and-quick-search.aspx&npage=/medicare-coverage-database/details/lcd-details.aspx&LCDId=26841&ContrId=300&ver=93&ContrVer=1&CtrctrSelected=300*1&Ctrctr=300&name=National+Government+Services%2c+Inc.+(National+Government+Services%2c+Inc.+(13202%2c+A+and+B+and+HHH+MA)  
Specialty-matched clinical peer review.
8. New York State Medicaid Update. October 2022. Volume 38. Number 12. Available at:  
[https://www.health.ny.gov/health\\_care/medicaid/program/update/2022/docs/mu\\_no12\\_oct22.pdf](https://www.health.ny.gov/health_care/medicaid/program/update/2022/docs/mu_no12_oct22.pdf)