

<b>Title: Botulinumtoxin Therapy</b>	<b>Division: Medical Management Department: Utilization Management</b>
<b>Approval Date: 8/17/2018</b>	<b>LOB: Medicaid, SNP, HARP, CHP, QHP, EP, Gold, Goldcare, Medicare, Ultracare</b>
<b>Effective Date: 8/17/2018</b>	<b>Policy Number: UM-MP235</b>
<b>Review Date: 6/16/2026</b>	<b>Cross Reference Number:</b>
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**I. POLICY DESCRIPTION:**

Neurotoxins, Botox (onabotulinumtoxinA), Dysport (abobotulinumtoxinA), Xeomin (incobotulinumtoxinA), Myobloc (rimabotulinumtoxinB)

**II. RESPONSIBLE PARTIES:**

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

**III. DEFINITIONS:**

- Botulinum toxin is a neurotoxic protein produced by the bacterium Clostridium botulinum and related species. It prevents the release of acetylcholine from axon endings at the neuromuscular junction, thus causing flaccid paralysis.

**IV. POLICY INITIAL APPROVAL:**

**For Medicare and Ultracare Only:**

<b>Botulinum Toxins Product(s)</b>	
<b>Preferred</b>	<b>Dysport</b> (AbobotulinumtoxinA) <b>Xeomin</b> (IncobotulinumtoxinA)
<b>Non-preferred</b>	<b>Botox</b> (OnabotulinumtoxinA) <b>Myobloc</b> (RimabotulinumtoxinB)

- A.** Non-preferred drugs will be considered medically necessary for beneficiaries/ members when ALL of the following criteria are met:
- Documented trial and failure with all preferred drugs listed above when indications overlap. See **Table 1** below
  - This policy is only applicable to members new to therapy. Members already on therapy with non-preferred drug(s) will not be subjected to this step therapy requirement. MetroPlus will utilize a 365-day lookback period and/or documentation of medical history stating member is already on therapy with non-preferred drug(s).
- B.** MetroPlusHealth determines medical necessity based on applicable Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). <https://www.cms.gov/medicare-coverage-database/search.aspx>

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**Table 1. Botulinum Toxin: Product and Indication**

Indication	Drug Name			
	Botox	Dysport	Myobloc	Xeomin
<b>Cervical Dystonia</b>	X	X	X	X
<b>Chronic Sialorrhea</b>	X	X	X	X
<b>Blepharospasm</b>	X			X
<b>Upper Limb Spasticity</b>	X	X		X
<b>Lower Limb Spasticity</b>	X	X		
<b>Chronic Migraine</b>	X			
<b>Overactive Bladder/Urinary Incontinence due to Detrusor Overactivity</b>	X			
<b>Primary Axillary Hyperhidrosis</b>	X	X	X	
<b>Strabismus</b>	X			
<b>Achalasia</b>	X			
<b>Anal Fissure</b>	X	X		

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**For Medicaid, SNP, HARP Plan members Only:** MetroPlusHealth determines medical necessity based on applicable New York State Fee-For-Service (FFS) clinical criteria.

[https://www.health.ny.gov/health\\_care/medicaid/program/practitioner\\_administered/ffs\\_practitioner\\_administer.htm](https://www.health.ny.gov/health_care/medicaid/program/practitioner_administered/ffs_practitioner_administer.htm)

**1. Chronic Migraine (Botox)**

- A. Member has chronic migraines defined by headaches greater than or equal to 15 days per month, with a headache lasting greater than or equal to 4 hours per day;

**APPROVE FOR 12 MONTHS**

**2. Overactive Bladder (Botox)**

- A. Member must have history of failure, contraindication, or intolerance to at least one of the following: An antimuscarinic agent OR a beta-3 adrenergic agonist.
  - a. oxybutynin immediate and extended release tabs, patch, gel;
  - b. tolterodine immediate and extended release;
  - c. fesoterodine fumarate - tablet, extended release; oral;
  - d. darifenacin hydrobromide - tablet, extended release; oral;
  - e. solifenacin succinate;
  - f. trospium immediate and extended release.

**APPROVE FOR 12 MONTHS**

**3. Chronic Sialorrhea (Botox, Dysport, Myobloc, Xeomin)**

- A. Member must have history of failure, contraindication, or intolerance to glycopyrrolate.

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**For all other LOBs:**

**POLICY: INITIAL REQUEST**

**1. CHRONIC MIGRAINE (18 years and older) (Botox)**

**A.** OnabotulinumtoxinA is indicated for the prophylaxis of headaches in adult patients with chronic migraine ( $\geq 15$  days per month with headache lasting 4 hours a day or longer) for patients who have not responded to, or are intolerant to a 2-month trial of at least three (3) medications selected from at least two (2) of the following classes of migraine headache prophylaxis medications in the past 12 months:

- a.** Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (e.g., losartan, valsartan, lisinopril);
- b.** Anti-depressants (e.g., amitriptyline, clomipramine, doxepin, mirtazapine, nortriptyline, protriptyline);
- c.** Anti-epileptic drugs (e.g., divalproex, gabapentin, topiramate, valproic acid);
- d.** Beta blockers (e.g., atenolol, metoprolol, nadolol, propranolol, timolol);
- e.** Calcium channel blockers (e.g., diltiazem, nifedipine, nimodipine, verapamil);
- f.** Calcitonin gene-related peptide (CGRP) Antagonists indicated for migraine prevention [e.g., erenumab (Aimovig), fremanezumab (Ajovy), galcanezumab (Emgality), eptinezumab (Vyepiti), atogepant (Qulipta), ubrogepant (Ubrelyv), and Rimegepant (Nurtec)];

**AND**

**B.** Member will not be on concurrent therapy with eptinezumab (Vyepiti);

**AND**

**C.** For continuing onabotulinumtoxinA therapy, the patients must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving additional onabotulinumtoxinA treatments;

**AND**

**D.** OnabotulinumtoxinA treatment injections for Chronic Migraines are to be performed by a Neurologist. Recommended minimum treatment interval is 12 weeks.

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**2. OVERACTIVE BLADDER/ URINARY INCONTINENCE DUE TO DETRUSOR OVERACTIVITY (5 years and older) (Botox)**

A. OnabotulinumtoxinA is indicated for the treatment of overactive bladder and or urinary incontinence due to detrusor overactivity in-patients who have not responded to, or is intolerant to a 3-month trial of at least two (2) anticholinergic medications in the past 12 months such as:

- a. oxybutynin immediate and extended release tabs, patch, gel;
- b. tolterodine immediate and extended release;
- c. fesoterodine fumarate - tablet, extended release; oral;
- d. darifenacin hydrobromide - tablet, extended release; oral;
- e. solifenacin succinate;
- f. trospium immediate and extended release;

**AND**

B. OnabotulinumtoxinA treatment injections for Overactive Bladder/ Urinary incontinence due to detrusor overactivity are to be performed by a Urologist, Urogynecologist or Plastic Surgeon.

**APPROVE FOR 12 MONTHS**

**3. SPASTICITY (Botox, Dysport, Xeomin)**

A. OnabotulinumtoxinA, abobotulinumtoxinA and incobotulinumtoxinA are indicated for the treatment of **upper limb spasticity** in patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb adductor (adductor pollicis), abductors (abductor polici brevis and abductor digitum minimus) and flexors (flexor pollicis longus). In pediatric patients 2 years and older, abobotulinumtoxinA in indicated for the treatment in upper limb spasticity excluding spasticity caused by cerebral palsy;

**AND**

B. OnabotulinumtoxinA and abobotulinumtoxinA are indicated for the treatment of **lower limb spasticity** in patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus);

**AND**

C. The requested drug may be considered for a patient who has not responded satisfactorily or is intolerant to a 3-month trial at least two (2) of the interventions below in the past 12 months:

- a. Trial of Skeletal muscle relaxants (dantrolene, baclofen);

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- b. Benzodiazepines (e.g. diazepam);
- c. Alpha2-adrenergic agonists (clonidine, tizanidine);
- d. Therapeutic interventions (physical therapy, occupational therapy, hippotherapy, aquatics) and physical modalities (ultrasonography, electrical stimulation, biofeedback);
- e. Positioning/orthotics (including taping, dynamic and static splints, wheelchairs, and standers);
- f. Surgical intervention (including selective dorsal rhizotomy and orthopedic procedures);

**AND**

**D.** Botulinum toxin treatment injections for spasticity are to be performed by a Neurologist. The recommended minimum interval between treatments is 12 weeks;

**AND**

**E.** Age limitations:

- a. OnabotulinumtoxinA: 2 years and older
- b. AbobotulinumtoxinA: 2 years and older
- c. IncobotulinumtoxinA: 18 years of age and older

**APPROVE FOR 12 MONTHS**

**4. CERVICAL DYSTONIA (Botox, Dysport, Myobloc, Xeomin)**

**A.** OnabotulinumtoxinA, abobotulinumtoxinA, rimabotulinumtoxinB and incobotulinumtoxinA are indicated for the treatment of adults with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia;

**AND**

**B.** Botulinum Toxin treatment injections for Cervical Dystonia are to be performed by a Physician;

**AND**

**C.** Age limitations

- a. OnabotulinumtoxinA: 16 years of age and older;
- b. AbobotulinumtoxinA: 18 years of age and older;
- c. RimabotulinumtoxinB: 18 years of age and older;
- d. IncobotulinumtoxinA: 18 years of age and older

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**5. SEVERE PRIMARY AXILLARY HYPERHIDROSIS (18 years and older) (Botox, Dysport, Myobloc)**

A. OnabotulinumtoxinA, rimabotulinumtoxinB and abobotulinumtoxinA are indicated for the treatment of severe primary axillary hyperhidrosis in adult patients who have experienced focal, visible, bilateral severe sweating for at least six (6) months duration without apparent cause with at least two (2) of the following characteristics:

- a. relatively symmetric;
- b. significant impairment in daily activities;
- c. age of onset less than 25 years;
- d. positive family history;
- e. cessation of focal sweating during sleep;
- f. History of medical complications (e.g., skin infections/functional impairments) or significant impact to activities of daily living (directly attributable to the condition);

**AND**

B. OnabotulinumtoxinA, rimabotulinumtoxinB and abobotulinumtoxinA are indicated for the treatment of severe primary axillary hyperhidrosis in adult patients who have not responded satisfactorily to or is intolerant to at least a 6-month trial to ONE of the following within the past 12 months:

- a. extra-strength antiperspirants (e.g., 20% aluminum chloride hexahydrate, 6.25% aluminum chloride hexahydrate boric acid, 2-5% tannic acid solutions)

**OR**

- b. topical agents (e.g., resorcinol, potassium permanganate, glycopyrronium);

**OR**

- c. oral agent (e.g., oral glycopyrrolate);

**AND**

C. Botulinum toxin treatment injections for Severe Primary Axillary Hyperhidrosis are to be performed by a Physician.

**APPROVE FOR 12 MONTHS**

**6. BLEPHAROSPASMS (Botox, Xeomin)**

A. OnabotulinumtoxinA and incobotulinumtoxinA are accepted as the first line treatment for patients with blepharospasm and/or hemifacial spasm as defined by ONE of the following:

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- a. If the upper and lower lid of the same eye and/or adjacent facial muscles, or brow are injected at the same surgery, the procedure is considered to be unilateral;

**OR**

- b. Bilateral procedures will only be considered when both eyes or both sides of the face are injected;

**AND**

- B. OnabotulinumtoxinA and incobotulinumtoxinA treatment injections for Blepharospasms are to be performed by a Neurologist or Ophthalmologist;

**AND**

- C. Age limitations:

- a. OnabotulinumtoxinA: 12 years of age and older
- b. IncobotulinumtoxinA: 18 years of age and older

**APPROVE FOR 12 MONTHS**

**7. STRABISMUS IN MEMBERS (12 years of age and older) (Botox)**

- A. OnabotulinumtoxinA is indicated for the treatment of strabismus in patients 12 years of age and above;

**AND**

- B. OnabotulinumtoxinA treatment injections for Strabismus are to be performed by a Neurologist or Ophthalmologist.

**APPROVE FOR 12 MONTHS**

**8. ACHALASIA (Botox)**

- A. OnabotulinumtoxinA for achalasia may be considered for the patient who has not responded satisfactorily to conventional therapy; is at high risk of complication from pneumatic dilation or surgical myotomy; has had treatment failure with pneumatic dilation or surgical myotomy; has had perforation from pneumatic dilation; has an epiphrenic diverticulum or hiatal hernia; or has esophageal varices;

**AND**

- B. OnabotulinumtoxinA treatment injections for Achalasia are to be performed by a Surgeon or Gastroenterologist.

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**9. ANAL FISSURE (Botox, Dysport)**

- A. OnabotulinumtoxinA and abobotulinumtoxinA are indicated for the treatment of chronic anal fissure and may be considered for the patient who has not responded satisfactorily to or is intolerant to a 2-month trial to ALL of the following in the past 12 months:
  - a. topical nitroglycerin;
  - AND**
  - b. a topical calcium channel blocker (e.g., nifedipine 0.2-0.5% gel, diltiazem 2% cream);
- AND**
- B. Botulinumtoxin treatment injections for Anal Fissure are to be performed by a Surgeon or Gastroenterologist.

**APPROVE FOR 12 MONTHS**

**10. SIALORRHEA (Botox, Dysport, Myobloc, Xeomin)**

- A. OnabotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB, and abobotulinumtoxinA are indicated for the treatment of sialorrhoea due to conditions such as motor neuron disease or Parkinson’s disease in those patients who have failed to respond to a 3-month trial of the following traditional therapies in the past 6 months unless they have a contraindication or intolerance to:
  - a. Anticholinergics (e.g., atropine, scopolamine or glycopyrrolate);
  - AND**
  - b. Speech therapy
- AND**
- B. Botulinum Toxin treatment injections for Sialorrhoea are to be performed by a Neurologist or Otolaryngologist;
- AND**
- C. Age limitations:
  - a. OnabotulinumtoxinA: 18 years of age and older
  - b. IncobotulinumtoxinA: 18 years of age and older
  - c. RimabotulinumtoxinB: 18 years of age and older
  - d. AbobotulinumtoxinA: 18 years of age and older

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**POLICY: RENEWAL REQUEST**

Clinical documentation supports positive response to therapy

For all conditions: **APPROVE FOR 12 MONTHS**

**BOTULINUMTOXIN TREATMENT GUIDELINES:**

**A. Overactive bladder/Urinary incontinence due to detrusor overactivity**

1. Botulinum toxin treatment injections for Overactive Bladder are to be performed by a Urologist or Urogynecologist.
2. OnabotulinumtoxinA
  - i. Overactive bladder: 100 units/ 12 weeks
  - ii. Urinary incontinence due to detrusor overactivity: 200 units/ 12 weeks

**B. Chronic Migraine**

1. Botulinum toxin treatment injections are to be performed by a Neurologist.
2. OnabotulinumtoxinA
  - i. 200 units / 12 weeks

**C. Pediatric lower limb spasticity**

1. OnabotulinumtoxinA
  - i. The recommended dose for treating pediatric lower limb spasticity is 4 Units/kg to 8 Units/kg divided among the affected muscles. The total dose of onabotulinumtoxinA administered per treatment session in the lower limb should not exceed 8 Units/kg or 300 Units, whichever is lower.
    1. Gastrocnemius medial head: 1 Unit/kg to 2 Units/kg divided in 2 sites
    2. Gastrocnemius lateral head: 1 Unit/kg to 2 Units/kg divided in 2 sites
    3. Soleus: 1 Unit/kg to 2 Units/kg divided in 2 sites
    4. Tibialis posterior: 1 Unit/kg to 2 Units/kg divided in 2 sites
2. AbobotulinumtoxinA:
  - i. The recommended dose for treating pediatric lower limb spasticity is 10 to 15 Units/kg per limb. The total dose per treatment session in the lower limb should not exceed 15 Units/kg or 1,000 units, whichever is less.

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1. Gastrocnemius: 6 – 9 units/kg in 1-4 sites
2. Soleus: 4-6 units/kg in 1-2 sites

**D. Adult lower limb spasticity**

1. OnabotulinumtoxinA

- a. The lowest recommended starting dose should be used and ≤50 units/site should be administered. May repeat therapy after 3 months. Note: Dose listed is total dose administered as divided into separate intramuscular injection(s):
  - i. Flexor digitorum longus: 50 units (divided into 2 sites)
  - ii. Flexor hallucis longus: 50 units (divided into 2 sites)
  - iii. Gastrocnemius lateral head: 75 units (divided into 3 sites)
  - iv. Gastrocnemius medial head: 75 units (divided into 3 sites)
  - v. Soleus: 75 units (divided into 3 sites)
  - vi. Tibialis posterior: 75 units (divided into 3 sites)

2. AbobotulinumtoxinA

- a. The maximum recommended total dose per treatment session in adults is 1500 Units
  - a. Flexor digitorum longus: 130 to 200 units (1 to 2 injections per muscle).
  - b. Flexor hallucis longus: 70 to 200 units (1 injection per muscle).
  - c. Gastrocnemius, medial head: 100 to 150 units (1 injection per muscle).
  - d. Gastrocnemius, lateral head: 100 to 150 units (1 injection per muscle).
  - e. Soleus: 330 to 500 units (3 injections per muscle).
  - f. Tibialis posterior: 200 to 300 units (2 injections per muscle).

**E. Pediatric upper limb spasticity**

a. OnabotulinumtoxinA

- i. The recommended dose for treating pediatric upper limb spasticity is 3 Units/kg to 6 Units/kg divided among the affected muscles. The total dose of onabotulinumtoxinA administered per treatment session in the upper limb should not exceed 6 Units/kg or 200 Units, whichever is lower.
  1. Biceps brachii: 1.5 Units/kg to 3 Units/kg divided in 4 sites

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2. Brachialis: 1 Unit/kg to 2 Units/kg divided in 2 sites
3. Brachioradialis 0.5 Units/kg to 1 Uit/kg divided in 2 sites
4. Flexor carpi radialis: 1 Unit/kg to 2 Units/kg divided in 2 sites
5. Flexor carpi ulnaris: 1 Unit/kg to 2 Units/kg givided in 2 sites
6. Flexor digitorum profundus: 0.5 Units/kg to 1 Unit/kg divided in 2 sites
7. Flexor digitorum sublimis: 0.5 Units/kg to 1 Unit/kg divided in 2 sites

**b. AbobotulinumtoxinA**

- i. The recommended dosing for upper limb spasticity, excluding spasticity caused by cerebral palsy: 8 Units/kg to 16 Units/kg per limb. The maximum recommended total dose administered per treatment session must not exceed 16 Units/kg or 640 Units, whichever is lower
  1. Biceps brachii: 3 Units/kg to 6 Units/kg divided in up to 2 sites
  2. Brachialis: 3 Units/kg to 6 Units/kg divided in up to 2 sites
  3. Brachioradialis 1.5 Units/kg to 3 Units/kg in 1 site
  4. Flexor carpi radialis: 2 Units/kg to 4 Units/kg in up to 2 sites
  5. Flexor carpi ulnaris: 1.5 Units/kg to 3 Units/kg up to 1 site
  6. Flexor digitorum profundus: 1 Units/kg to 2 Units/kg in up to 1 site
  7. Flexor digitorum sublimis: 1.5 Units/kg to 3 Units/kg in up to 4 sites
  8. Pronator teres: 1 Units/kg to 2 Units/kg in up to 1 site
  9. Pronator quadratus: 0.5 Units/kg to 1 Units/kg in up to 1 site

**F. Adult upper limb spasticity**

**a. OnabotulinumtoxinA**

- i. The lowest recommended starting dose should be used and ≤50 units/site should be administered. May repeat therapy after 3 months. Note: Dose listed is total dose administered as divided into separate intramuscular injection(s):
  1. Adductor pollicis: 20 units (1 site)
  2. Biceps brachii: 100 to 200 units (divided into 4 sites)
  3. Flexor digitorum profundus: 30 to 50 units (1 site)
  4. Flexor digitorum sublimis: 30 to 50 units (1 site)
  5. Flexor carpi radialis: 12.5 to 50 units (1 site)
  6. Flexor carpi ulnaris: 12.5 to 50 units (1 site)
  7. Flexor pollicis longus: 20 units (1 site)

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2. IncobotulinumtoxinA:

i. Dosing should be separated by at least 12 weeks. Note: Dose listed is total dose administered as divided into separate intramuscular injection(s):

1. Flexor digitorum superficialis: 25 to 100 units (divided into 2 sites)
2. Flexor digitorum profundus: 25 to 100 units (divided into 2 sites)
3. Flexor carpi radialis: 25 to 100 units (1-2 sites)
4. Flexor carpi ulnaris: 20 to 100 units (1-2 sites)
5. Brachioradialis: 25 to 100 units (1-3 sites)
6. Biceps: 50 to 200 units (1-4 sites)
7. Brachialis: 25 to 100 units (1-2 sites)
8. Pronator quadratus: 10 to 50 units (1 site)
9. Pronator teres: 25 to 75 units (1-2 sites)
10. Flexor pollicis longus: 10 to 50 units (1 site)
11. Adductor pollicis: 5 to 30 units (1 site)
12. Flexor pollicis brevis/ Opponens pollicis: 5 to 30 units (1 site)

3. AbobotulinumtoxinA:

i. The maximum recommended total dose per treatment session in adults is 1500 Units

1. Brachialis: 200 to 400 units (1 to 2 injections per muscle)
2. Brachioradialis: 100 to 200 units (1 to 2 injections per muscle).
3. Biceps brachii: 200 to 400 units (1 to 2 injections per muscle).
4. Flexor carpi radialis: 100 to 200 units (1 to 2 injections per muscle).
5. Flexor carpi ulnaris: 100 to 200 units (1 to 2 injections per muscle).
6. Flexor digitorum profundus: 100 to 200 units (1 to 2 injections per muscle).
7. Flexor digitorum superficialis: 100 to 200 units (1 to 2 injections per muscle).
8. Ponator teres: 100 to 200 units (1 injection per muscle)

**G. Cervical dystonia**

1. OnabotulinumtoxinA:

- i. Maximum of 50 units/site
- ii. Maximum of 100 units injected to sternocleidomastoid muscles

2. RimabotulinumtoxinB:

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- i. Maximum of 10,000 units per treatment session
- 3. IncobotulinumtoxinA:
  - i. Initial dose: maximum of 120 units divided and injected among infected muscles
- 4. AbobotulinumtoxinA:
  - i. Maximum dose of 1,000 units per treatment session

**H. Severe primary axillary hyperhidrosis**

- a. OnabotulinumtoxinA
  - i. Maximum of 50 units per Axilla
- b. AbobotulinumtoxinA
  - i. 100-200 units per axilla
- c. RimabotulinumtoxinB
  - i. 2,000 units per axilla

**I. Blepharospasms**

- a. Botulinum toxin treatment injections for Strabismus and or Blepharospasms are to be performed by a Neurologist or Ophthalmologist.
- b. OnabotulinumtoxinA
  - i. ≤200 units in 30-day period
- c. IncobotulinumtoxinA:
  - i. Maximum of 1,000 units per treatment session (50 units for each eye)

**J. Strabismus**

- a. Botulinum toxin treatment injections for Strabismus are to be performed by a Neurologist.
- b. OnabotulinumtoxinA
  - i. Maximum of 25 units for any one muscle

**K. Chronic Sialorrhea**

- a. OnabotulinumtoxinA
  - i. Recommended dose varies based on gland(s) being injected
- b. IncobotulinumtoxinA
  - i. The recommended dose is 100 units (30 units on both of the parotid glands and 20 units on both of the submandibular glands). Dosages should be separated by at least 12 weeks
- c. RimabotulinumtoxinB

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i. Maximum dose of 1,500 units per parotid gland, 250 units per submandibular gland, 3,500 units per treatment session

**d. AbobotulinumtoxinA**

i. 15 to 75 units injected per gland (submandibular, parotid or both) either unilaterally or bilaterally with intervals of 4 to 6 months between treatments

**L. Achalasia**

**a. OnabotulinumtoxinA**

i. Maximum dose of 100 units per treatment session

**M. Anal Fissure**

**a. OnabotulinumtoxinA**

i. Maximum dose of 25 units per treatment session

**2. AbobotulinumtoxinA**

ii. 90 to 150 units in 2 divided doses injected into the internal anal sphincter on each side of the anterior midline

**V. LIMITATIONS/ EXCLUSIONS:**

- a. The FDA has issued a black box warning for all botulinim toxin treatments for the spread of toxin effect. That the botulinum toxin effect may, in some cases be observed beyond the site of local injection. The symptoms include asthenia, muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties.
- b. Safety and effectiveness of onabotulinumtoxinA have not been established for: prophylaxis of episodic migraine (14 headache days or fewer per month). Recommended treatment interval is a minimum of every 12 weeks as deemed necessary.
- c. For onabotulinumtoxinA - as vials are available in increments of 50 units, the minimum necessary vials will be approved for each request. (E.G. 150 units will be approved for a request for 125 units)
- d. Treatment of hyperhidrosis in body areas other than axillary will not be covered.
  - 1. The safety and effectiveness of botulinum toxin for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive botulinum toxin for palmar hyperhidrosis and facial hyperhidrosis, respectively.
- e. Injections exceeding the frequencies depicted in the Treatment Guidelines section are not considered medically necessary.
- f. Treatment of the following conditions are not considered medically necessary, as there is insufficient evidence to support effectiveness:

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1. Spastic conditions not listed in the ICD-10 table
  2. Biliary dyskinesia
  3. Irritable bowel
  4. Pain conditions not associated with spasticity/dystonia to include myofascial pain and fibromyalgia
  5. Plantar hyperhidrosis
- g. Treatment with botulinum toxin is not intended to substitute for usual standard of care rehabilitation regimens.
  - h. For IncobotulinumtoxinA, infections at the injection site are a contraindication for administration.
  - i. Medicare will allow payment for one injection per site regardless of the number of injections made into the site. 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 extremity and/or trunk muscle(s).
  - j. 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.
  - k. Treatment of wrinkles (ICD-10-CM codes L90.8 and L91.8) using botulinum toxin is considered to be cosmetic, and is not covered.
  - l. Payment will not be made for any spastic condition of smooth muscle, such as spastic colon and biliary dyskinesia, or of any spastic condition not listed under "ICD-10-CM Codes That Support Medical Necessity."
  - m. The cost of special syringes is not separately payable. They are considered part of the surgical procedure.
  - n. When HCPCS code J0585, J0586, J0587 or J0588 is denied, the related injection code(s) will also be subject to denial.
  - o. The below NDCs for Botox cosmetic (J0585), Dysport (J0586), and Xeomin (J0588) are excluded as per NYS Department of Health:
    1. J0585
      - i. 00023-3919-50, 00023-9232-50 & 00023-9232-01 are excluded NDCs
    2. J0586
      - i. 00299-5962-30 is an excluded NDC
    3. J0588
      - i. 46783-0161-01 & 46783-0160-01 are excluded NDCs

**VI. APPLICABLE PROCEDURE CODES:**

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<b>CPT/HCPCS Codes</b>	<b>Description</b>
43201	ESOPHAGOSCOPY, 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
64611	CHEMODENERVATION OF PAROTID AND SUBMANDIBULAR SALIVARY GLANDS, BILATERAL
64612	CHEMODENERVATION OF MUSCLE(S); MUSCLE(S) INNERVATED BY FACIAL NERVE, UNILATERAL (EG, FOR BLEPHAROSPASM, 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) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
64644	CHEMODENERVATION OF ONE EXTREMITY; 5 OR MORE MUSCLES
64645	CHEMODENERVATION OF ONE EXTREMITY; EACH ADDITIONAL EXTREMITY, 5 OR MORE MUSCLES (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
64646	CHEMODENERVATION OF TRUNK MUSCLE(S); 1-5 MUSCLE(S)
64647	CHEMODENERVATION OF TRUNK MUSCLE(S); 6 OR MORE MUSCLES
64650	CHEMODENERVATION OF ECCRINE GLANDS; BOTH AXILLAE
64653	CHEMODENERVATION OF ECCRINE GLANDS; OTHER AREA(S) (EG, SCALP, FACE, NECK), PER DAY
67345	CHEMODENERVATION OF EXTRAOCULAR MUSCLE
J0585	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
J0586	INJECTION, ABOBOTULINUMTOXINA, 5 UNITS

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J0587	INJECTION, RIMABOTULINUMTOXINB, 100 UNITS
J0588	INJECTION, INCOBOTULINUMTOXIN A, 1 UNIT

**VII. APPLICABLE DIAGNOSIS CODES:**

<b>ICD-10 Codes</b>	<b>Description</b>	<b>Limitations</b>
K11.7	Disturbances of salivary secretion	CPT code 64611 (used for injection of salivary glands for sialorrhea)
K22.0	Achalasia of cardia	For CPT codes 43201, 43236
K60.0	Acute anal fissure	For CPT code 46505
K60.1	Chronic anal fissure	For CPT code 46505
K60.2	Anal fissure, unspecified	For CPT code 46505
G83.4	Cauda equina syndrome	For CPT code 52287
N31.0	Uninhibited neuropathic bladder, not elsewhere classified	For CPT code 52287
N31.1	Reflex neuropathic bladder, not elsewhere classified	For CPT code 52287
N31.8	Other neuromuscular dysfunction of bladder	For CPT code 52287
N31.9	Neuromuscular dysfunction of bladder, unspecified	For CPT code 52287
N32.81	Overactive bladder	For CPT code 52287
N36.44	Muscular disorders of urethra	For CPT code 52287
G24.4	Idiopathic orofacial dystonia	For CPT code 64612
G24.5	Blepharospasm	For CPT code 64612
G51.2	Melkersson's syndrome	For CPT code 64612
G51.3	Clonic hemifacial spasm	For CPT code 64612
G51.4	Facial myokymia	For CPT code 64612
G51.8	Other disorders of facial nerve	For CPT code 64612
G24.3	Spasmodic torticollis	For CPT code 64616
M43.6	Torticollis	For CPT code 64616
J38.5	Laryngeal spasm	For CPT code 64617
G11.4*	Hereditary spastic paraplegia	For CPT code 64642, 64643, 64644, 64645, 64646 and
G24.1	Genetic torsion dystonia	
G24.2*	Idiopathic nonfamilial dystonia	

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G24.8*	Other dystonia	<p>64647</p> <p>Use ICD-10-CM code M62.411 through M62.838 (spasm of muscle) to report treatment of spasticity secondary to spastic hemiplegia and hemiparesis.</p> <p>Group 8 Medical Necessity ICD-10 Codes Asterisk Explanation:</p> <p>*ICD-10-CM codes with an asterisk (*) are to be used only when there is spasticity of central nervous system origin.</p>
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	
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	
G82.21*	Paraplegia, complete	
G82.22*	Paraplegia, incomplete	

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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	
G83.81*	Brown-Sequard syndrome	
G83.82*	Anterior cord syndrome	
G83.89*	Other specified paralytic syndromes	
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	

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169.034*	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side	
169.041*	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right dominant side	
169.042*	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left dominant side	
169.043*	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side	
169.044*	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side	
169.051*	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side	
169.052*	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side	
169.053*	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side	
169.054*	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side	
169.061*	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting right dominant side	
169.062*	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting left dominant side	
169.063*	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting right non-dominant side	

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169.064*	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage affecting left non-dominant side	
169.065*	Other paralytic syndrome following nontraumatic subarachnoid hemorrhage, bilateral	
169.131*	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side	
169.132*	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side	
169.133*	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side	
169.134*	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side	
169.141*	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side	
169.142*	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side	
169.143*	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side	
169.144*	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side	
169.151*	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side	
169.152*	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side	

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169.153*	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side	
169.154*	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side	
169.161*	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting right dominant side	
169.162*	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting left dominant side	
169.163*	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting right non-dominant side	
169.164*	Other paralytic syndrome following nontraumatic intracerebral hemorrhage affecting left non-dominant side	
169.165*	Other paralytic syndrome following nontraumatic intracerebral hemorrhage, bilateral	
169.231*	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side	
169.232*	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side	
169.233*	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side	
169.234*	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side	
169.241*	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side	

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169.242*	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side	
169.243*	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side	
169.244*	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side	
169.251*	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side	
169.252*	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side	
169.253*	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side	
169.254*	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side	
169.261*	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting right dominant side	
169.262*	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting left dominant side	
169.263*	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting right non-dominant side	
169.264*	Other paralytic syndrome following other nontraumatic intracranial hemorrhage affecting left non-dominant side	
169.265*	Other paralytic syndrome following other nontraumatic intracranial hemorrhage, bilateral	
169.331*	Monoplegia of upper limb following cerebral infarction affecting right dominant side	

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169.332*	Monoplegia of upper limb following cerebral infarction affecting left dominant side	
169.333*	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side	
169.334*	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side	
169.341*	Monoplegia of lower limb following cerebral infarction affecting right dominant side	
169.342*	Monoplegia of lower limb following cerebral infarction affecting left dominant side	
169.343*	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side	
169.344*	Monoplegia of lower limb following cerebral infarction affecting left non-dominant side	
169.351*	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side	
169.352*	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side	
169.353*	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side	
169.354*	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side	
169.361*	Other paralytic syndrome following cerebral infarction affecting right dominant side	
169.362*	Other paralytic syndrome following cerebral infarction affecting left dominant side	
169.363*	Other paralytic syndrome following cerebral infarction affecting right non-dominant side	
169.364*	Other paralytic syndrome following cerebral infarction affecting left non-dominant side	
169.365*	Other paralytic syndrome following cerebral infarction, bilateral	
169.831*	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side	
169.832*	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side	

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169.833*	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side	
169.834*	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side	
169.841*	Monoplegia of lower limb following other cerebrovascular disease affecting right dominant side	
169.842*	Monoplegia of lower limb following other cerebrovascular disease affecting left dominant side	
169.843*	Monoplegia of lower limb following other cerebrovascular disease affecting right non-dominant side	
169.844*	Monoplegia of lower limb following other cerebrovascular disease affecting left non-dominant side	
169.851*	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side	
169.852*	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side	
169.853*	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side	
169.854*	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side	
169.861*	Other paralytic syndrome following other cerebrovascular disease affecting right dominant side	
169.862*	Other paralytic syndrome following other cerebrovascular disease affecting left dominant side	
169.863*	Other paralytic syndrome following other cerebrovascular disease affecting right non-dominant side	
169.864*	Other paralytic syndrome following other cerebrovascular disease affecting left non-dominant side	

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169.865*	Other paralytic syndrome following other cerebrovascular disease, bilateral	
169.931*	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side	
169.932*	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side	
169.933*	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side	
169.934*	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side	
169.941*	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side	
169.942*	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side	
169.943*	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side	
169.944*	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side	
169.951*	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side	
169.952*	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side	
169.953*	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side	
169.954*	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side	
169.961*	Other paralytic syndrome following unspecified cerebrovascular disease affecting right dominant side	
169.962*	Other paralytic syndrome following unspecified cerebrovascular disease affecting left dominant side	

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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	
M62.411	Contracture of muscle, right shoulder	
M62.412	Contracture of muscle, left shoulder	
M62.421	Contracture of muscle, right upper arm	
M62.422	Contracture of muscle, left upper arm	
M62.431	Contracture of muscle, right forearm	
M62.432	Contracture of muscle, left forearm	
M62.441	Contracture of muscle, right hand	
M62.442	Contracture of muscle, left hand	
M62.451	Contracture of muscle, right thigh	
M62.452	Contracture of muscle, left thigh	
M62.461	Contracture of muscle, right lower leg	
M62.462	Contracture of muscle, left lower leg	
M62.471	Contracture of muscle, right ankle and foot	
M62.472	Contracture of muscle, left ankle and foot	
M62.48	Contracture of muscle, other site	
M62.49	Contracture of muscle, multiple sites	
M62.831	Muscle spasm of calf	
M62.838	Other muscle spasm	
L74.510	Primary focal hyperhidrosis, axilla	For CPT codes 64650, 64653 _Indication is for severe primary axillary hyperhidrosis
H02.041	Spastic entropion of right upper eyelid	For CPT code 67345
H02.042	Spastic entropion of right lower eyelid	For CPT code 67345
H02.044	Spastic entropion of left upper eyelid	For CPT code 67345
H02.045	Spastic entropion of left lower eyelid	For CPT code 67345
H02.141	Spastic ectropion of right upper eyelid	For CPT code 67345
H02.142	Spastic ectropion of right lower eyelid	For CPT code 67345

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H02.144	Spastic ectropion of left upper eyelid	For CPT code 67345
H02.145	Spastic ectropion of left lower eyelid	For CPT code 67345
H49.01	Third [oculomotor] nerve palsy, right eye	For CPT code 67345
H49.02	Third [oculomotor] nerve palsy, left eye	For CPT code 67345
H49.03	Third [oculomotor] nerve palsy, bilateral	For CPT code 67345
H49.11	Fourth [trochlear] nerve palsy, right eye	For CPT code 67345
H49.12	Fourth [trochlear] nerve palsy, left eye	For CPT code 67345
H49.13	Fourth [trochlear] nerve palsy, bilateral	For CPT code 67345
H49.21	Sixth [abducent] nerve palsy, right eye	For CPT code 67345
H49.22	Sixth [abducent] nerve palsy, left eye	For CPT code 67345
H49.23	Sixth [abducent] nerve palsy, bilateral	For CPT code 67345
H49.31	Total (external) ophthalmoplegia, right eye	For CPT code 67345
H49.32	Total (external) ophthalmoplegia, left eye	For CPT code 67345
H49.33	Total (external) ophthalmoplegia, bilateral	For CPT code 67345
H49.41	Progressive external ophthalmoplegia, right eye	For CPT code 67345
H49.42	Progressive external ophthalmoplegia, left eye	For CPT code 67345
H49.43	Progressive external ophthalmoplegia, bilateral	For CPT code 67345
H49.881	Other paralytic strabismus, right eye	For CPT code 67345
H49.882	Other paralytic strabismus, left eye	For CPT code 67345
H49.883	Other paralytic strabismus, bilateral	For CPT code 67345
H50.00	Unspecified esotropia	For CPT code 67345
H50.011	Monocular esotropia, right eye	For CPT code 67345
H50.012	Monocular esotropia, left eye	For CPT code 67345
H50.021	Monocular esotropia with A pattern, right eye	For CPT code 67345
H50.022	Monocular esotropia with A pattern, left eye	For CPT code 67345
H50.031	Monocular esotropia with V pattern, right eye	For CPT code 67345
H50.032	Monocular esotropia with V pattern, left eye	For CPT code 67345
H50.041	Monocular esotropia with other noncomitancies, right eye	For CPT code 67345
H50.042	Monocular esotropia with other noncomitancies, left eye	For CPT code 67345
H50.05	Alternating esotropia	For CPT code 67345
H50.06	Alternating esotropia with A pattern	For CPT code 67345
H50.07	Alternating esotropia with V pattern	For CPT code 67345
H50.08	Alternating esotropia with other noncomitancies	For CPT code 67345
H50.10	Unspecified exotropia	For CPT code 67345

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H50.111	Monocular exotropia, right eye	For CPT code 67345
H50.112	Monocular exotropia, left eye	For CPT code 67345
H50.121	Monocular exotropia with A pattern, right eye	For CPT code 67345
H50.122	Monocular exotropia with A pattern, left eye	For CPT code 67345
H50.131	Monocular exotropia with V pattern, right eye	For CPT code 67345
H50.132	Monocular exotropia with V pattern, left eye	For CPT code 67345
H50.141	Monocular exotropia with other noncomitancies, right eye	For CPT code 67345
H50.142	Monocular exotropia with other noncomitancies, left eye	For CPT code 67345
H50.15	Alternating exotropia	For CPT code 67345
H50.16	Alternating exotropia with A pattern	For CPT code 67345
H50.17	Alternating exotropia with V pattern	For CPT code 67345
H50.18	Alternating exotropia with other noncomitancies	For CPT code 67345
H50.21	Vertical strabismus, right eye	For CPT code 67345
H50.22	Vertical strabismus, left eye	For CPT code 67345
H50.30	Unspecified intermittent heterotropia	For CPT code 67345
H50.311	Intermittent monocular esotropia, right eye	For CPT code 67345
H50.312	Intermittent monocular esotropia, left eye	For CPT code 67345
H50.32	Intermittent alternating esotropia	For CPT code 67345
H50.331	Intermittent monocular exotropia, right eye	For CPT code 67345
H50.332	Intermittent monocular exotropia, left eye	For CPT code 67345
H50.34	Intermittent alternating exotropia	For CPT code 67345
H50.40	Unspecified heterotropia	For CPT code 67345
H50.411	Cyclotropia, right eye	For CPT code 67345
H50.412	Cyclotropia, left eye	For CPT code 67345
H50.42	Monofixation syndrome	For CPT code 67345
H50.43	Accommodative component in esotropia	For CPT code 67345
H50.50	Unspecified heterophoria	For CPT code 67345
H50.51	Esophoria	For CPT code 67345
H50.52	Exophoria	For CPT code 67345
H50.53	Vertical heterophoria	For CPT code 67345
H50.54	Cyclophoria	For CPT code 67345
H50.55	Alternating heterophoria	For CPT code 67345
H50.60	Mechanical strabismus, unspecified	For CPT code 67345
H50.611	Brown's sheath syndrome, right eye	For CPT code 67345

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H50.612	Brown's sheath syndrome, left eye	For CPT code 67345
H50.69	Other mechanical strabismus	For CPT code 67345
H50.811	Duane's syndrome, right eye	For CPT code 67345
H50.812	Duane's syndrome, left eye	For CPT code 67345
H50.89	Other specified strabismus	For CPT code 67345
H51.0	Palsy (spasm) of conjugate gaze	For CPT code 67345
H51.11	Convergence insufficiency	For CPT code 67345
H51.12	Convergence excess	For CPT code 67345
H51.21	Internuclear ophthalmoplegia, right eye	For CPT code 67345
H51.22	Internuclear ophthalmoplegia, left eye	For CPT code 67345
H51.23	Internuclear ophthalmoplegia, bilateral	For CPT code 67345
H51.8	Other specified disorders of binocular movement	For CPT code 67345
H51.9	Unspecified disorder of binocular movement	For CPT code 67345
G43.011	Migraine without aura, intractable, with status migrainosus	For CPT code 64615  Coverage will only be allowed for those patients with chronic daily headaches (headache disorders occurring greater than 15 days a month - in many cases daily with a duration of four or more hours - for a period of at least 3 months) who have significant disability due to the headaches, and have been refractory to standard and usual conventional therapy. The etiology of the chronic daily headache may be
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	

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		<p>chronic tension-type headache or chronic migraine (CM). CM is characterized by headache on &gt;15 days per month, of which at least 8 headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment. For continuing Botulism toxin therapy the patients must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving Botulinum toxin. (Please see Indications and Limitations)</p>
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**REVISION LOG:**

<b>REVISIONS</b>	<b>DATE</b>
Creation date	8/17/2018
FIDA Removed from LOB	2/1/2019
Revised	2/1/2019
Unit change - Migraine	6/21/2019
Annual Review	6/23/2020
Revised – Migraine past treatment medication list	12/20/2021
Revised – Update to indications, addition of all botulinumtoxin therapies	1/28/2022
Revised limitation section to include excluded NDCs for Botox cosmetic, Dysport & Xeomin	5/31/2022
Annual Review	1/31/2023
Annual Review	1/22/2024
Remove hyperlink to CMS LCD	6/24/2024
Updates	11/25/24
Updates – Inclusion of NYS FFS Criteria	6/16/2026

**Approved:**

**Date:**

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**Sanjiv Shah, MD  
Chief Medical Officer**

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