Oscar Clinical Guideline: Botulinum Toxin (CG033, Ver. 15)

Botulinum Toxin

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Botulinum toxins are a class of injectable medications that block the nerves responsible for controlling muscle function. The paralysis of targeted muscles typically occurs within 2 to 5 days after administration and can last for 2 to 3 months. There are seven different types (A-G) of Botulinum toxin, but only types A and B are approved for clinical use:

- There are currently five botulinum toxin preparations available in the US, including:
    - four type A preparations (abobotulinumtoxinA [Dysport®], daxibotulinumtoxinA-lanm [Daxxify®], incobotulinumtoxinA [Xeomin®], and onabotulinumtoxinA [Botox®, Botox® Cosmetic])
        - Two additional forms of botulinum toxin are available for cosmetic purposes only (Jeuveau® [prabotulinumtoxinA-xvfs], and Letybo® [letibotulinumtoxinA-wlbg]).
    - one type B preparation (rimabotulinumtoxinB [Myobloc®])
- Botulinum toxin preparations must be prescribed and administered by a licensed physician or medical provider.

Botulinum toxins have pharmacological uses in the treatment of various medical conditions characterized by muscle spasms or overactivity, such as cerebral palsy, stroke, and spinal cord disorders. In these conditions, Botulinum toxins are used to reduce muscle tone, relieve pain, and improve functional ability. Botulinum toxins are also used to treat other conditions, such as chronic migraine, hyperhidrosis, and strabismus.

Botulinum toxins can also be used for cosmetic purposes, such as decreasing wrinkles, but such use is not considered medically necessary by the Plan. In cosmetic applications, Botulinum toxins are used to reduce the appearance of wrinkles by relaxing the muscles responsible for facial expressions. The effects of cosmetic Botulinum toxin injections typically last for 3 to 4 months.

NOTE: The Plan may require the use of preferred medications as the first-line treatment. Please refer to the following applicable Plan Clinical Guideline for a comprehensive list of our preferred and non-preferred drugs on the medical benefit:

- Commercial Preferred Physician-Administered Specialty Drugs (CG052).
- Botulinum Toxins - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG088).

Definitions

"Achalasia" is a failed relaxation of the lower esophageal sphincter resulting in painful spasms and/or regurgitation of food.

"Blepharospasm" refers to uncontrolled blinking or spasms of the eyelids.

"Botulinum Toxins" refer to the seven serologically distinct neurotoxins derived from the bacterium *Clostridium botulinum*. These agents differ in their synthesis and the specific bacterium strain from which they are isolated. Botulinum toxins function by inhibiting acetylcholine release at the neuromuscular junction to cause flaccid paralysis of muscles.

"Cervical Dystonia" (also known as **"Spasmodic Torticollis"**) refers to painful contraction of the neck muscles causing twisting or tilting of the head to one side.

"**Chronic anal fissure**" is a tear in the skin of the anus that persists for more than 8 weeks.

"**Chronic migraine"** is a type of migraine headache that occurs at least 15 days per month for more than three months.

"Detrusor Hyperactivity" (also known as **"Bladder Overactivity"**) refers to spasms of the bladder muscles resulting in pain or incontinence.

"**Detrusor sphincter dyssynergia (DSD)"** is a medical condition that affects the coordination between the bladder and the muscles around the urethra, which is called the external urinary sphincter.

"**Essential tremors"** is a neurological disorder characterized by involuntary shaking or trembling movements, usually affecting the arms and hands but sometimes involving the head and other parts of the body.

"Hyperhidrosis" refers to inappropriate, excessive sweating.

"**Hemifacial spasms"** is a neurological disorder characterized by involuntary contractions of the facial muscles on one side of the face.

"**Hyperhidrosis Disease Severity Scale (HDSS)**" is a tool used to assess the severity of hyperhidrosis, a condition characterized by excessive sweating beyond what is necessary for regulating body temperature. The HDSS is a simple and quick questionnaire that consists of only one question and is rated on a scale from 1 to 4:

1. No interference with daily activities
2. Noticeable but not causing interference with daily activities
3. Some interference with daily activities
4. Severe interference with daily activities

The HDSS is used by healthcare professionals to determine the impact of hyperhidrosis on a patient's quality of life and to guide treatment decisions. Patients with HDSS scores of 3 or 4 are considered to have severe hyperhidrosis and may require more aggressive treatment options, such as prescription antiperspirants, oral medications, or minimally invasive procedures like botulinum toxin injections or iontophoresis. Patients with HDSS scores of 1 or 2 may benefit from less invasive treatments like topical antiperspirants or lifestyle modifications.

"**Lower extremity**" Refers to the leg, knee, ankle, and foot.

"Muscle Spasms" refer to the involuntary contractions of one or more muscles.

"**Neurogenic"** refers to a condition or disorder that is caused by or related to problems with the nervous system.

"**Oromandibular dystonias (OMD)"** refer to a group of neurological movement disorders that affect the muscles of the jaw, mouth, and face. OMD can cause involuntary muscle contractions that result in abnormal movements and postures, such as jaw clenching, teeth grinding, lip pursing, or tongue protrusion. OMD can be classified into several types based on the location and pattern of muscle contractions, including jaw-opening, jaw-closing, or mixed OMD.

"**Overactive bladder**" is a condition in which the muscles in the bladder contract involuntarily and cause a sudden urge to urinate.

"**Prophylaxis**" is a preventative treatment intended to stop or reduce the recurrence of a disease or condition.

"Sialorrhea" (also known as **"Ptyalism"**) refers to excess salivation or drooling.

"**Spasmodic dysphonia**" is a neurological disorder that affects the muscles of the voice box, causing spasms and interruptions in speech.

"**Spasticity**" is a condition characterized by increased muscle tone, which can cause stiffness, spasms, or involuntary movements.

"**Strabismus**" is a vision disorder in which the eyes are not properly aligned and point in different directions.

"**Temporomandibular disorders (TMD)"** refer to a group of conditions that affect the temporomandibular joint (TMJ) and the muscles of the jaw and face.

"**Upper extremity**" refers to the arm, shoulder, and hand.

"**Urge incontinence**" is a type of urinary incontinence characterized by the sudden, strong urge to urinate that is followed by an involuntary loss of urine.

"**Urinary incontinence**" is a condition in which a person cannot control their bladder, leading to the involuntary loss of urine.

"**Urodynamic testing"** is a medical diagnostic procedure that evaluates how well the lower urinary tract (including the bladder and urethra) is functioning. The test measures various parameters, such as bladder pressure, urine flow rate, and capacity, to help diagnose conditions that affect the urinary system, such as incontinence, urinary tract obstruction, or nerve or muscle problems.

Clinical Indications

Medical Necessity Criteria for Initial Authorization

OnabotulinumtoxinA (Botox) (J0585)

The Plan deems **OnabotulinumtoxinA (Botox)** medically necessary for the following indications if the disease-specific criteria for initial requests are met (refer to **Continued Care** for reauthorization criteria or **Table 1** for standard initial/retreatment authorization durations):

A. Achalasia, when **BOTH** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., gastroenterologist, endoscopist, ENT)***; and***
    b. Documented evidence of **ALL** of the following
        i. Confirmed diagnosis with esophageal manometry; ***and***
        ii. Alternative causes of the symptoms (e.g., esophageal stricture, carcinoma, schatzki's ring, or extrinsic compression), have been ruled out by upper endoscopy and/or adequately treated***; and***
        iii. Presence of progressive dysphagia to solids and liquids; ***and***
        iv. **ONE** of the following:
            1. Pneumatic dilation or surgical myotomy (i.e., laparoscopic Heller myotomy, or peroral endoscopic myotomy (POEM)) has been attempted but was unsuccessful***; or***
            2. The member was not a good candidate for the procedure***; or***
            3. The member refused treatment/surgery.

B. Axillary hyperhidrosis or palmar hyperhidrosis, when **ALL** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., dermatologist, neurologist)**; *and***
    b. The member is 18 years of age or older**; *and***
    c. Documented evidence of **ALL** of the following:
        i. Severe hyperhidrosis, defined as **ONE** of the following:

1. a score of 3 or 4 on the Hyperhidrosis Disease Severity Scale**; *or***
2. The impact of excessive sweating on quality of life has been significant, causing interference with daily activities (e.g., social, professional) and leading to feelings of anxiety and embarrassment**; *and***

ii. Alternative causes of the symptoms (e.g., hyperthyroidism, lifestyle factors), have been ruled out or adequately treated**; *and***

iii. The member is unable to use, or has tried and failed first-line management with **BOTH** of the following:

1. lifestyle measures such as avoiding known triggers and tight clothing**; *and***
2. using antiperspirants (e.g., aluminum chloride hexahydrate).

C. Blepharospasm, when **ALL** of the following are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., ophthalmologist, neurologist, movement disorder specialist); ***and***

b. Member is 12 years of age or older**; *and***

c. Documented evidence of **BOTH** of the following:

i. Diagnosis of **ONE** or more of the following:

1. Benign essential blepharospasm; ***or***
2. Blepharospasm associated with dystonia; ***or***
3. Blepharospasm associated with facial nerve disorders such as Bell palsy; ***and***

ii. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to neuromuscular diseases (e.g., myasthenia gravis).

D. Cervical dystonia (i.e., spasmodic torticollis), when **ALL** of the following are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***

b. Member is 16 years of age or older**; *and***

c. Documented evidence of **ALL** of the following:

i. Symptoms (e.g., abnormal head positioning, neck pain, limited range of motion, muscle spasms) have been present for at least 6 months**; *and***

ii. Neck pain and abnormal head tilt/torsion adversely affects range of motion and daily functioning; ***and***

iii. Sustained involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); ***and***

iv. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to:

1. Neuromuscular disease (e.g., myasthenia gravis); ***or***
2. Chronic neuroleptic treatment; ***or***
3. Fixed muscle contractures.

E. Chronic anal fissure, when **ALL** of the following are met:
   a. The request is by a provider specialist who will administer botulinum toxin (e.g., gastroenterologist, colon or rectal surgeon); ***and***
   b. Documented evidence of **ALL** of the following:
      i. At least 2 months of symptoms, including **ONE** or more of the following:
         1. Nocturnal pain and bleeding; ***or***
         2. Post-defecation pain; ***and***
      ii. The member is unable to use **ALL**, or has tried and failed **ONE** of the following:
         1. topical nitrates (e.g., Nitroglycerin 0.2% or 0.4% rectal ointment)**; *or***
         2. topical calcium channel blockers (e.g., Diltiazem 2% rectal gel, nifedipine 0.2% or 0.5% rectal ointment)**; *and***
   c. The member does **NOT** have documented evidence of ANY of the following:
      i. Anal fistula; ***or***
      ii. Hemorrhoids; ***or***
      iii. HIV; ***or***
      iv. Inflammatory bowel disease; ***or***
      v. Perianal abscess; ***or***
      vi. Perianal cancer; ***or***
      vii. Prior perianal surgical intervention.

F. Chronic migraine prophylaxis, when **ALL** of the following are met:
   a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, headache specialist); ***and***
   b. Member is 18 years of age or older; ***and***
   c. Documented evidence of **ALL** of the following:
      i. Diagnosis of migraine headache (with or without aura) per International Classification of Headache Disorders criteria, defined as meeting **ALL** of the following criteria:
         1. Headache is characterized by at least **TWO** of the following:
            a. Pulsating quality; ***and/or***
            b. Unilateral location; ***and/or***
            c. Moderate to severe pain/intensity; ***and/or***
            d. Aggravation by physical activity; ***and***
         2. Symptoms are associated with at least **ONE** of the following:

a. Nausea and/or vomiting; ***or***
b. Photophobia (sensitivity to light) and phonophobia (sensitivity to sound); ***and***

3. Other potential causes of headache have been ruled out; ***and***

ii. The member has chronic migraines, defined as headache occurring on 15 or more days per month for more than three months, which, on at least 8 days per month, has the features of migraine headache**; *and***

iii. The member is unable to use **ALL**, or has adequately tried and failed an 8-week trial of at least **TWO** (2) preventative therapies, from at least **TWO** (2) of the following drug classes:

1. Anticonvulsants (such as topiramate, divalproex, sodium valproate); ***and/or***
2. Antidepressants (such as amitriptyline, nortriptyline, venlafaxine); ***and/or***
3. Beta blockers (such as propranolol, metoprolol); ***AND***

d. The member does **NOT** have documented evidence of ANY of the following:

i. Neuromuscular disease (e.g., myasthenia gravis); ***or***

ii. Botox (onabotulinumtoxinA) will be used concomitantly with a preventative calcitonin gene-related peptide (CGRP) antagonist for migraine headache prophylaxis.

- *i.e. the following CGRP antagonist products when used for preventive treatment of migraine include Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec (rimegepant), Qulipta (atogepant), Vyepti (eptinezumab).*
- *i.e. this restriction does not apply to the use of CGRP antagonists for acute/abortive treatment of migraine, such as Emgality (galcanezumab), Nurtec (rimegepant), or Ubrelvy (ubrogepant).*
- *<u>NOTE:</u> Please refer to the Plan's pharmacy benefit and Plan Clinical Guideline Anti-migraine Agents/ Calcitonin Gene-Related Peptide (CGRP) Antagonists and Serotonin Receptor 5-HT1F Agonists (PG008).*

G. Essential tremors, when **BOTH** of the following criteria are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist, otolaryngology); ***and***

b. Documented evidence of **BOTH** of the following:

i. ONE of the following diagnosis:

1. disabling head and neck tremor**; *or***
2. disabling essential hand tremor**; *and***

ii. The member is unable to use **ALL**, or has tried and failed **TWO** (2) of the following:
    1. Propranolol (immediate-release or extended-release)***; and/or***
    2. Primidone***; and/or***
    3. Gabapentin; ***and/or,***
    4. Topiramate.

H. Hemifacial spasm, when **ALL** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***
    b. Member is 12 years of age or older; ***and***
    c. Documented evidence of **BOTH** of the following:
        i. Diagnosis of hemifacial spasm in muscles innervated by the facial nerve (cranial nerve VII); ***and***
        ii. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to neuromuscular diseases (e.g. myasthenia gravis).

I. Oromandibular dystonias (i.e., cranial dystonia), when **BOTH** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist, orofacial pain specialist, otolaryngologist)***; and***
    b. Documented evidence of **BOTH** of the following:
        i. characterized by continuous, bilateral, asynchronous muscle spasms in the face, jaw, pharynx, and tongue***; and***
        ii. causing difficulty in jaw closing or opening and interfering with fluid and food intake and speech.

J. Overactive bladder with urge incontinence, when **ALL** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., urologist); ***and***
    b. Member is 18 years of age or older; ***and***
    c. Documented evidence of **BOTH** of the following:
        i. Urodynamic testing confirms urinary incontinence with urgency***; and***
        ii. Symptoms had not been adequately managed with **BOTH** of the following:
            1. Behavioral therapies (such as bladder training and pelvic floor muscle therapy), for at least 8 weeks***; and***
            2. A minimum of **THREE (3)** pharmacologic therapies, with either inadequate response or intolerable side effects, each tried for at least 4 weeks:

a. Anticholinergic (i.e., antimuscarinics) therapy, such as darifenacin (Enablex), fesoterodine (Toviaz), oxybutynin (Ditropan XL), solifenacin (Vesicare), tolterodine (Detrol/Detrol LA), or trospium (Sanctura/Sanctura XR)**; *and/or***
b. Beta-3 Adrenergic Agonists, such as Gemtesa (vibegron) or Myrbetriq (miraberon)**; *and***

d. The member does **NOT** have documented evidence of **ANY** of the following:
    i. acute urinary retention; ***or***
    ii. acute urinary tract infection.

K. Sialorrhea, when **BOTH** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, physical medicine and rehabilitation (PM&R), or ENT); ***and***
    b. Documented evidence of **ALL** of the following:
        i. Chronic sialorrhea resulting from a neurological condition (e.g., Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury); ***and***
        ii. Complications such as recurrent infection or chronic skin breakdown that have failed treatment with topical agents or lifestyle modifications**; *and***
        iii. The member is unable to use **ALL**, or has adequately tried and failed **two** (2) months of pharmacotherapy with **ONE** (1) of the following:
            1. Benztropine**; *and/or***
            2. Glycopyrrolate**; *and/or***
            3. Scopolamine.

L. Spasmodic dysphonia (i.e., laryngeal dystonia), when **BOTH** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., gastroenterologist, endoscopist, ENT); ***and***
    b. Documented evidence of **BOTH** of the following:
        i. Adductor-type spasmodic dysphonia confirmed by fiberoptic laryngoscopy**; *and***
        ii. Moderate to severe phonation difficulties.

M. Spasticity of the upper and/or lower extremity, when **ALL** of the following criteria are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, PM&R); ***and***
    b. The member is characterized by **ONE** of the following:
        i. Members greater than the age of 2 with spasticity due to cerebral palsy or stroke who are receiving ongoing rehabilitation; ***or***
        ii. Members 18 years of age or older with **ONE** of the following:

1. Spasticity secondary to multiple sclerosis or other demyelinating diseases of the central nervous system; ***or***
2. Spasticity secondary to spinal cord injury**; *or***
3. Post-stroke spasticity; ***and***

c. Documentation of **ALL** of the following:
   i. Joint is not affected by fixed contracture**; *and***
   ii. Abnormal muscle tone that interferes with daily functioning or is expected to result in joint contracture with further growth; ***and***
   iii. Treatment is expected to improve functioning and/or allow for further therapeutic rehabilitation**; *and***
   iv. Surgical intervention is the only alternative option; ***and***
   v. If the request is for the treatment of lower limb spasticity, the member has tried and failed appropriate non-surgical medical treatments (e.g., pharmacologic and physical therapies).

N. Strabismus, when **ALL** of the following are met:
   a. The request is by a provider specialist who will administer botulinum toxin (e.g., ophthalmologist); ***and***
   b. The member is 12 years of age or older; ***and***
   c. The member does **NOT** have documented evidence of **ANY** of the following:
      i. Duane's syndrome with lateral rectus weakness**; *or***
      ii. Likely to have a spontaneous recovery**; *or***
      iii. Restrictive strabismus**; *or***
      iv. Strabismus secondary to prior surgical overrecession of the ocular antagonist muscle.

O. Upper extremity focal dystonia (e.g., writer's cramp), when **ALL** of the following are met:
   a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***
   b. The member is 16 years of age or older; ***and***
   c. Documented evidence of **ALL** of the following:
      i. Significant pain and/or abnormal hand or forearm positioning that adversely affects daily functioning**; *and***
      ii. Failure of at least two months of conservative therapy and/or lifestyle modification.

P. Urinary incontinence due to detrusor overactivity (i.e., detrusor instability or detrusor hyperreflexia) or detrusor-sphincter dyssynergia, when **ALL** of the following are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., urologist)**; *and***
b. The member is 5 years of age or older**; *and***
c. Documented evidence of **ALL** of the following:
    i. The condition is associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis, Parkinson's disease, cerebral palsy, stroke)**; *and***
    ii. Symptoms had not been adequately managed with **ALL** of the following:
        1. Behavioral therapies (such as bladder training and pelvic floor muscle therapy) for 8 to 12 weeks**; *and***
        2. The member is unable to use ALL or has tried and failed at least **ONE** of the following anticholinergic (i.e. antimuscarinics) therapies such as darifenacin (Enablex), fesoterodine (Toviaz), oxybutynin (Ditropan XL), solifenacin (Vesicare), tolterodine (Detrol/Detrol LA), or trospium (Sanctura/Sanctura XR) for 4 to 8 weeks (inadequate response or intolerable adverse effects)**; *and***
        3. **The member meets ONE** of the following:
            a. Balloon sphincter dilation or surgical treatment has been attempted but was unsuccessful**; *or***
            b. The member was not a candidate due to comorbidities**; *or***
            c. The member refused surgery; ***and***
d. The member does **NOT** have documented evidence of **ANY** of the following:
    i. urinary tract infection (UTI)**; *or***
    ii. urinary retention or postvoid residuals (PVR) greater than 200 mL unless the patient is receiving intermittent catheterization as part of the overall treatment plan.

<u>AbobotulinumtoxinA (Dysport) (J0586)</u>

The Plan deems AbobotulinumtoxinA (Dysport) medically necessary for the following indications if the disease-specific criteria for initial requests are met (refer to **Continued Care** for reauthorization criteria or **Table 1** for standard initial/retreatment authorization durations):

A. Axillary hyperhidrosis, when **ALL** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., dermatologist, neurologist)**; *and***
    b. The member is 18 years of age or older**; *and***
    c. Documented evidence of **ALL** of the following:
        i. Severe primary axillary hyperhidrosis, defined as **ONE** of the following:

1. a score of 3 or 4 on the Hyperhidrosis Disease Severity Scale**; *or***
2. The impact of excessive sweating on quality of life has been significant, causing interference with daily activities (e.g., social, professional) and leading to feelings of anxiety and embarrassment**; *and***

ii. Alternative causes of the symptoms (e.g., hyperthyroidism, lifestyle factors), have been ruled out or adequately treated**; *and***

iii. The member is unable to use, or has tried and failed first-line management with **BOTH** of the following:

1. lifestyle measures such as avoiding known triggers and tight clothing**; *and***
2. using antiperspirants (e.g., aluminum chloride hexahydrate)

B. Blepharospasm or hemifacial spasms, when **ALL** of the following are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., ophthalmologist, neurologist, movement disorder specialist); ***and***

b. Member is 18 years of age or older; ***and***

c. Documented evidence of **BOTH** of the following:

i. Diagnosis of **ONE** or more of the following:

1. Benign essential blepharospasm; ***or***
2. Blepharospasm associated with dystonia; ***or***
3. Blepharospasm associated with facial nerve disorders such as Bell palsy; **or**
4. Hemifacial spasm involving the orbicularis oculi muscle; ***and***

ii. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to neuromuscular diseases (e.g., myasthenia gravis).

C. Cervical dystonia (i.e., spasmodic torticollis), when **ALL** of the following are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***

b. Member is 16 years of age or older**; *and***

c. Documented evidence of **ALL** of the following:

i. Symptoms (e.g., abnormal head positioning, neck pain, limited range of motion, muscle spasms) have been present for at least 6 months**; *and***

ii. Neck pain and abnormal head tilt/torsion adversely affects range of motion and daily functioning; ***and***

iii. Sustained involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); ***and***

iv. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to:
    1. Neuromuscular disease (e.g., myasthenia gravis); ***or***
    2. Chronic neuroleptic treatment; ***or***
    3. Fixed muscle contractures.

D. Chronic anal fissure, when **ALL** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., gastroenterologist, colon or rectal surgeon); ***and***
    b. Documented evidence of **ALL** of the following:
        i. At least 2 months of symptoms, including **ONE** or more of the following:
            1. Nocturnal pain and bleeding; ***or***
            2. Post-defecation pain; ***and***
        ii. The member is unable to use **ALL**, or has tried and failed **ONE** of the following:
            1. topical nitrates (e.g., Nitroglycerin 0.2% or 0.4% rectal ointment)**; *or***
            2. topical calcium channel blockers (e.g., Diltiazem 2% rectal ointment, nifedipine 0.2% or 0.5% rectal ointment)**; *and***
    c. The member does **NOT** have documented evidence of **ANY** of the following:
        i. Anal fistula; ***or***
        ii. Hemorrhoids; ***or***
        iii. HIV; ***or***
        iv. Inflammatory bowel disease; ***or***
        v. Perianal abscess; ***or***
        vi. Perianal cancer; ***or***
        vii. Prior perianal surgical intervention.

E. Sialorrhea, when **BOTH** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, PM&R, or ENT); ***and***
    b. Documented evidence of **ALL** of the following:
        i. Chronic sialorrhea resulting from a neurological condition (e.g., Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury); ***and***
        ii. Complications such as recurrent infection or chronic skin breakdown that have failed treatment with topical agents or lifestyle modifications**; *and***
        iii. The member is unable to use **ALL**, or has adequately tried and failed **TWO** (2) months of pharmacotherapy with **ONE** (1) of the following:
            1. Benztropine**; *or***
            2. Glycopyrrolate**; *or***

3. Scopolamine.

F. Spasticity of the upper and/or lower extremity, when **ALL** of the following criteria are met:
   a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, PM&R); ***and***
   b. The member is characterized by **ONE** of the following:
      i. Members greater than the age of 2 with spasticity due to cerebral palsy or stroke who are receiving ongoing rehabilitation; ***or***
      ii. Members 18 years of age or older with **ONE** of the following:
         1. Spasticity secondary to multiple sclerosis or other demyelinating diseases of the central nervous system; ***or***
         2. Spasticity secondary to spinal cord injury***; or***
         3. Post-stroke spasticity; ***and***
   c. Documentation of **ALL** of the following:
      i. Joint is not affected by fixed contracture***; and***
      ii. Abnormal muscle tone that interferes with daily functioning or is expected to result in joint contracture with further growth; ***and***
      iii. Treatment is expected to improve functioning and/or allow for further therapeutic rehabilitation***; and***
      iv. Surgical intervention is the only alternative option; ***and***
      v. If the request is for the treatment of lower limb spasticity, the member has tried and failed appropriate non-surgical medical treatments (e.g., pharmacologic and physical therapies).

G. Upper extremity focal dystonia (e.g., writer's cramp), when **ALL** of the following are met:
   a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***
   b. The member is 16 years of age or older; ***and***
   c. Documented evidence of **ALL** of the following:
      i. Significant pain and/or abnormal hand or forearm positioning that adversely affects daily functioning***; and***
      ii. Failure of at least two months of conservative therapy and/or lifestyle modification.

<u>RimabotulinumtoxinB (Myobloc) (J0587)</u>

The Plan deems RimabotulinumtoxinB (Myobloc) medically necessary for the following indications if the disease-specific criteria for initial requests are met (refer to **Continued Care** for reauthorization criteria or **Table 1** for standard initial/retreatment authorization durations):

A. Cervical dystonia (i.e., spasmodic torticollis), when **ALL** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***
    b. Member is 18 years of age or older; ***and***
    c. Documented evidence of **ALL** of the following:
        i. Symptoms (e.g., abnormal head positioning, neck pain, limited range of motion, muscle spasms) have been present for at least 6 months**; *and***
        ii. Neck pain and abnormal head tilt/torsion adversely affects range of motion and daily functioning; ***and***
        iii. Sustained involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); ***and***
        iv. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to:
            1. Neuromuscular disease (e.g., myasthenia gravis); ***or***
            2. Chronic neuroleptic treatment; ***or***
            3. Fixed muscle contractures.

B. Sialorrhea, when **ALL** of the following are met:
    a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, PM&R, or ENT); ***and***
    b. Member is 18 years of age or older**; *and***
    c. Documented evidence of **ALL** of the following:
        i. Chronic sialorrhea resulting from a neurological condition (e.g., Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury); ***and***
        ii. Complications such as recurrent infection or chronic skin breakdown that have failed treatment with topical agents or lifestyle modifications**; *and***
        iii. The member is unable to use **ALL**, or has adequately tried and failed **two** (2) months of pharmacotherapy with **ONE** (1) of the following:
            1. Benztropine**; *or***
            2. Glycopyrrolate**; *or***
            3. Scopolamine.

IncobotulinumtoxinA (Xeomin) (J0588)

The Plan deems **IncobotulinumtoxinA (Xeomin)** medically necessary for the following indications if the disease-specific criteria for initial requests are met (refer to **Continued Care** for reauthorization criteria or **Table 1** for standard initial/retreatment authorization durations):

A. Blepharospasm or hemifacial spasms, when **ALL** of the following are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., ophthalmologist, neurologist, movement disorder specialist); ***and***
b. Member is 18 years of age or older; ***and***
c. Documented evidence of **BOTH** of the following:
    i. Diagnosis of **ONE** or more of the following:
        1. Benign essential blepharospasm; ***or***
        2. Blepharospasm associated with dystonia; ***or***
        3. Blepharospasm associated with facial nerve disorders such as Bell palsy; or
        4. Hemifacial spasm involving the orbicularis oculi muscle; ***and***
    ii. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to neuromuscular diseases (e.g., myasthenia gravis).

B. Cervical dystonia (i.e., spasmodic torticollis), when **ALL** of the following are met:
a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***
b. Member is 18 years of age or older; ***and***
c. Documented evidence of **ALL** of the following:
    i. Symptoms (e.g., abnormal head positioning, neck pain, limited range of motion, muscle spasms) have been present for at least 6 months***; and***
    ii. Neck pain and abnormal head tilt/torsion adversely affects range of motion and daily functioning; ***and***
    iii. Sustained involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); ***and***
    iv. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to:
        1. Neuromuscular disease (e.g., myasthenia gravis); ***or***
        2. Chronic neuroleptic treatment; ***or***
        3. Fixed muscle contractures.

C. Sialorrhea, when **ALL** of the following are met:
a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, PM&R, or ENT); ***and***
b. Member is 2 years of age or older***; and***
c. Documented evidence of **ALL** of the following:
    i. Chronic sialorrhea resulting from a neurological condition (e.g., Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury); ***and***

ii. Complications such as recurrent infection or chronic skin breakdown that have failed treatment with topical agents or lifestyle modifications**; *and***

iii. The member is unable to use **ALL**, or has adequately tried and failed **two** (2) months of pharmacotherapy with **ONE (1)** of the following:

1. Benztropine**; *or***
2. Glycopyrrolate**; *or***
3. Scopolamine.

D. Spasticity of the upper limb, when **ALL** of the following criteria are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, PM&R); ***and***

b. The member is characterized by **ONE** of the following:

i. Members 2 to 17 years of age and **ONE** of the following:

1. the spasticity is not caused by cerebral palsy**; *or***
2. with spasticity due to cerebral palsy who are receiving ongoing rehabilitation; ***or***

ii. Members 18 years of age or older:

1. Spasticity secondary to multiple sclerosis or other demyelinating diseases of the central nervous system; ***or***
2. Spasticity secondary to spinal cord injury**; *or***
3. Post-stroke spasticity; ***and***

c. Documentation of **ALL** of the following:

i. Joint is not affected by fixed contracture**; *and***

ii. Abnormal muscle tone that interferes with daily functioning or is expected to result in joint contracture with further growth; ***and***

iii. Treatment is expected to improve functioning and/or allow for further therapeutic rehabilitation**; *and***

iv. Surgical intervention is the only alternative option**; *and***

v. If the request is for the treatment of lower limb spasticity, the member has tried and failed appropriate non-surgical medical treatments (e.g., pharmacologic and physical therapies).

DaxibotulinumtoxinA-lanm (Daxxify) (J0589)

The Plan deems **DaxibotulinumtoxinA-lanm (Daxxify)** medically necessary for the following indications if the disease-specific criteria for initial requests are met (refer to **Continued Care** for reauthorization criteria or **Table 1** for standard initial/retreatment authorization durations):

A. Cervical dystonia (i.e., spasmodic torticollis), when **ALL** of the following are met:

a. The request is by a provider specialist who will administer botulinum toxin (e.g., neurologist, movement disorder specialist); ***and***
b. Member is 18 years of age or older; ***and***
c. Documented evidence of **ALL** of the following:
    i. Symptoms (e.g., abnormal head positioning, neck pain, limited range of motion, muscle spasms) have been present for at least 6 months***; and***
    ii. Neck pain and abnormal head tilt/torsion adversely affects range of motion and daily functioning; ***and***
    iii. Sustained involuntary contractions in the neck muscles (e.g splenius, trapezius, posterior cervical, or sternocleidomastoid); ***and***
    iv. Alternative causes of the symptoms have been ruled out or adequately treated, including but not limited to:
        1. Neuromuscular disease (e.g., myasthenia gravis); ***or***
        2. Chronic neuroleptic treatment; ***or***
        3. Fixed muscle contractures.

Continued Care

Medical Necessity Criteria for Reauthorization

Except for specific conditions outlined elsewhere, the Plan considers continuing botulinum toxin treatment medically necessary if, at the end of the initial trial period:

A. A positive response is documented in the medical record, which should typically last for 3 months; ***and***
B. The member would continue to meet the clinical criteria for the specific botulinum toxin agent in the absence of further treatment; ***and***
C. The prescribing clinician provides an expected duration and frequency of ongoing treatment, which may require ongoing approval.
    NOTE: Treatment with botulinum toxin more frequently than every 3 months for a covered condition, regardless of diagnosis, is generally not considered medically necessary.
D. For chronic migraine prophylaxis with OnabotulinumtoxinA (Botox), after the initial trial period, which is defined as 6 months or a maximum of 2 treatments, the Plan considers continuing treatment medically necessary if the member experiences **ONE (1)** of the following:
    a. At least a 50% reduction in monthly migraine days; ***or***
    b. At least 2 fewer migraine days per month; ***or***
    c. At least a reduction of 7 headache days over a one-month period compared to the pre-treatment average; ***or***

d. A clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
    i. Migraine Disability Assessment (MIDAS)
        1. Reduction of ≥5 points when baseline score is 11-20; ***or***
        2. Reduction of ≥30% when baseline score is >20; ***or***
    ii. Migraine Physical Function Impact Diary (MPFID)
        1. Reduction of ≥5 points; ***or***
    iii. Headache Impact Test (HIT-6)
        1. Reduction of ≥5 points.

Criteria for Discontinuing Treatment

Botulinum toxin treatment is generally no longer considered medically necessary and should be discontinued, except as outlined for specific conditions elsewhere, when the following criteria are met:

A. Lack of documented clinical response after initial trial; ***or***
B. In cases where the initial trial was successful, lack of documented clinical response to two consecutive treatments precludes treatment at that site for a period of at least one year***; or***
C. For chronic migraine prophylaxis using OnabotulinumtoxinA (Botox), if the patient does not respond adequately after the initial trial period, defined as six months or a maximum of two treatments.

General Recommendations for Time to Retreatment and Dosing

Table 1 provides general recommendations for:

A. the time to retreatment with botulinum toxin agents, assuming that all other clinical criteria remain met. These recommendations may differ for individual members but should not occur more frequently than every three months. If requests for more frequent injection frequency are made, documentation of medical necessity should be provided.
B. the doses (in units) of botulinum toxin agents, assuming that all other clinical criteria are met. Although the recommended doses may vary by individual member and condition, they should not be exceeded regardless of indication. If injection dosages exceeding the recommended amounts are requested, further review and documentation of medical necessity may be required. The following table is provided for reference purposes only.

Table 1: Dosage and retreatment information for botulinum toxin regimens by indication

Botox (onabotulinumtoxinA)				
Indication	**Initial dose**	**Subsequent**	**Retreatment**	**Additional Considerations**

		Dose		
Unless otherwise noted in the indication-specific dosing, total maximum dose per 3 months are as follows: ● In pediatric patients <18 years, the maximum cumulative dose is 10 units/kg or 340 units, whichever is less. ● In adolescents & adults ≥18 years treated for 1 or more indications, the maximum cumulative dose should not exceed 400 units (i.e., ≤400 units per 3 months).				
Achalasia	20 to 25 units to each of the 4 quadrants in the lower esophageal sphincter		3 months	Maximum recommended dose is 100 units/course Residual lower esophageal sphincter tone of less than 18 mmHg after botulinum injection is a predictor of a good response
Blepharospasm	1.25–2.5 units per injection site	maximum dose per site: 5 units	3 months	Dose during subsequent treatment sessions may be increased by up to two-fold if initial response is insufficient (e.g., the duration of effect is <2 months) Cumulative dose: ≤200 units in 30-day period (i.e., maximum dose of 100 units per eye in a three-month period)
	Typically, 4-6 injection sites are used per affected eye.			
Cervical dystonia	50-200 units total	50-300 units total	3 months	Studies have documented a mean dose of 236 units divided among affected muscles (range: 198-300 units). Dose should be divided across all injected sites; Max 50 units/site The total dose injected into the sternocleidomastoid muscle should be limited to 100 units or less to decrease the risk of dysphagia.
Chronic anal fissure	5-100 units		2-4 months	Generally injected into the internal anal sphincter, with half on the right and the remainder into the left

Chronic migraine prophylaxis	155 units total		3 months	given as multiple injections divided among 7 head and neck muscles
Head/Neck Area Muscle(s)			**Total Dose Per Muscle**	**No. of Injection Sites per Muscle**
Frontalis			20 units	4 sites
Corrugator			10 units	2 sites
Procerus			5 units	1 site
Occipitalis			30 units	6 sites
Temporalis			40 units	8 sites
Trapezius			30 units	6 sites
Cervical paraspinal muscle group			20 units	4 sites
Total dose per treatment session			**155 units**	**31 sites**
Essential tremors, hand	50-100 units		3-4 months	Injected into the affected hand, divided among multiple injection sites
Essential tremors, head and neck	100-200 units		3-4 months	Injected into the affected muscles in the neck and/or head, divided among multiple injection sites
Hemifacial spasm	12–25 units administered into the inferior and superior orbicularis oculi, buccolabial, and/or platysma muscles. Typically, 20-30 injection sites are used on the affected side of the face, with a starting dosage of 2.5-5 units per injection site.		3 months	Cumulative dose: ≤200 units in 30-day period (i.e., maximum dose of 200 units per treatment session)
Hyperhidrosis, Axillary	50 units/axilla		4 months	Injections should be evenly distributed into multiple sites (10 to 15)
Hyperhidrosis, Palmar	100–120 units	100–165 units per palm	3 months	Inject among multiple (e.g., 50–60) sites in the hyperhidrotic area of

				each palm Studies have used doses of 200 units per palm
Laryngeal dysphonia	1-5 units/muscle	1-5 units/muscle	3 months	Typical doses range from 1-6 units in studies
Oromandibular dystonias (i.e., cranial dystonia)	10-50 units injected into each affected muscle		3-4 months	Total dose not to exceed 100 units per treatment session
Overactive bladder	100 units per treatment		3 months	Dose should divided across 20 injection sites
Sialorrhea	10-40 units/side	10-40 units/side	3 months	Total dose should be divided across parotid and submandibular if injecting both
Spasticity, Adult Upper Limb	75 Units to 400 Units divided among selected muscles; ≤50 units per site		3 months	Dose listed is total dose administered as divided separate intramuscular injection(s)
	● Adductor pollicis: 20 units (1 site). ● Biceps brachii: 60 to 200 units (divided into 2 to 4 sites). ● Brachialis: 30 to 50 units (divided into 1 to 2 sites). ● Brachioradialis: 45 to 75 units (divided into 1 to 2 sites). ● Flexor carpi radialis: 12.5 to 50 units (1 site). ● Flexor carpi ulnaris: 12.5 to 50 units (1 site). ● Flexor digitorum profundus: 30 to 50 units (1 site). ● Flexor digitorum sublimes: 30 to 50 units (1 site). ● Flexor pollicis brevis/opponens pollicis: 5 to 25 units (1 site). ● Flexor pollicis longus: 20 units (1 site). ● Lumbricals/interossei: 5 to 10 units (1 site). ● Pronator teres: 15 to 25 units (1 site). ● Pronator quadratus: 10 to 50 units (1 site). Stroke-related upper limb spasticity ● Adductor pollicis: 20 units (1 to 2 sites) ● Biceps brachii: 100 to 200 units (up to 4 sites) ● Flexor digitorum profundus: 15 to 50 units (1 to 2 sites)			

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<tr><td></td><td colspan="3">

Flexor digitorum sublimes: 15 to 50 units (1 to 2 sites)
Flexor carpi radialis: 15 to 60 units (1 to 2 sites)
Flexor carpi ulnaris: 10 to 50 units (1 to 2 sites)
Flexor pollicis longus: 20 units (1 to 2 sites)

</td></tr>
<tr><td rowspan="2">Spasticity, Adult Lower Limb</td><td>300 Units to 400 Units divided among 5 muscles; ≤50 units per site</td><td>3 months</td><td>Dose listed is total dose administered as divided separate intramuscular injection(s)</td></tr>
<tr><td colspan="3">

Flexor digitorum longus: 50 units (divided into 2 sites)
Flexor hallucis longus: 50 units (divided into 2 sites)
Gastrocnemius lateral head: 75 units (divided into 3 sites)
Gastrocnemius medial head: 75 units (divided into 3 sites)
Soleus: 75 units (divided into 3 sites)
Tibialis posterior: 75 units (divided into 3 sites)

</td></tr>
<tr><td rowspan="3">Spasticity, Associated with Cerebral Palsy in Pediatric Patients</td><td>Maximum dose per treatment session: 3–6 units/kg for large muscles, 1–2 units/kg for small muscles; maximum dose of 50 units per injection site</td><td>3 months</td><td>Maximum recommended total dose administered during a single treatment session should not exceed 12 units/kg or 400 units, whichever is less.</td></tr>
<tr><td colspan="3">Upper extremity: 3 to 6 units/kg total per session divided up amongst affected muscles; maximum dose per site: 50 units/site; maximum total dose per treatment session in the upper limb: 6 units/kg or 200 units total, whichever is less.

Biceps brachii: 1.5 to 3 units/kg divided in 4 sites
Brachialis: 1 to 2 units/kg divided in 2 sites
Brachioradialis: 0.5 to 1 unit/kg divided in 2 sites
Flexor carpi radialis: 1 to 2 units/kg divided in 2 sites
Flexor carpi ulnaris: 1 to 2 units/kg divided in 2 sites
Flexor digitorum profundus: 0.5 to 1 unit/kg divided in 2 sites
Flexor digitorum sublimis: 0.5 to 1 unit/kg divided in 2 sites

</td></tr>
<tr><td colspan="3">Lower extremity: 4 to 8 units/kg total per session divided up amongst affected muscles; maximum dose per site: 50 units/site; maximum total dose per treatment session in the lower limb or visit: 8 units/kg or 300 units total, whichever is less.

Gastrocnemius lateral head: 1 to 2 units/kg divided in 2 sites
Gastrocnemius medial head: 1 to 2 units/kg divided in 2 sites
Soleus: 1 to 2 units/kg divided in 2 sites
Tibialis posterior: 1 to 2 units/kg divided in 2 sites

</td></tr>
</table>

Strabismus	• Vertical muscles and for horizontal strabismus <20 prism diopters: 1.25 to 2.5 units in any one muscle • Horizontal strabismus of 20 to 50 prism diopters: 2.5 to 5 units in any one muscle • Persistent VI nerve palsy ≥1 month: 1.25 to 2.5 units in the medial rectus muscle		3 months	Max dose as a single injection for any one muscle is 25 units. Subsequent doses for patients experiencing incomplete paralysis of the target may be increased up to twice the previous administered dose.
Upper extremity focal dystonia	20-80 units/limb	20-200 units/limb	3 months	Total dose should be injected across affected muscles Studies have used doses of 200-360 units per treatment session.
Urinary incontinence due to detrusor overactivity secondary to neurologic condition	Adults: 200 units per treatment		3 months	given as 30 separate injections of approximately 6.7 units each into the detrusor muscle (avoiding the trigone)
	Children ≥5 years and <18 years, weight ≥34 kg: 200 units per treatment			administered as 20 injections
	Children ≥5 years and <18 years, weight <34 kg: 6 units/kg per treatment			administered as 20 injections
Dysport (abobotulinumtoxinA)				
Indication	**Initial dose**	**Subsequent Dose**	**Retreatment**	**Additional Considerations**
Axillary hyperhidrosis	100-200 units/axilla	100-500 units/axilla	3 months	Injections should be evenly distributed into multiple sites ~1 to 2 cm apart (10 to 20 injections)
Blepharospasm or hemifacial spasm	120 units subcutaneously per eye: 20-40 units/injection	80 units per eye: 20 units/injection	3 months	Cumulative dose: <60 units/eye or 120 units/both eyes per 3 month period after the initial dose
Cervical dystonia	250-500 units	250-1000 units	3 months	Dose should be divided among all treated muscles, retreatment should be no greater than 250 units

				more than prior treatment dose
Chronic anal fissure	90 to 150 units in 2 divided doses		2-4 months	injected into the internal anal sphincter on each side of the anterior midline Some studies have supported use of two injections of 90 units (180 units total)
Sialorrhea	15 to 75 units injected per gland (submandibular, parotid or both) either unilaterally or bilaterally		4-6 months	Injection should be into parotid and/or submandibular gland
Spasticity of upper/lower extremity (Adult)	Maximum recommended total dose (upper and lower limbs combined) is 1,500 units ● upper limb spasticity, total doses of 500 and 1,000 units divided among selected muscles ● lower limb spasticity, total doses of 1,000 and 1,500 units divided among selected muscles		3-5 months	Maximum total dose (including upper AND lower limbs combined) not to exceed 1500 units per 3 month period.
	Upper limbs: ● Brachialis: 200 to 400 units (1 to 2 injections per muscle). ● Brachioradialis: 100 to 200 units (1 to 2 injections per muscle). ● Biceps brachii: 200 to 400 units (1 to 2 injections per muscle). ● Flexor carpi radialis: 100 to 200 units (1 to 2 injections per muscle). ● Flexor carpi ulnaris: 100 to 200 units (1 to 2 injections per muscle). ● Flexor digitorum profundus: 100 to 200 units (1 to 2 injections per muscle). ● Flexor digitorum superficialis: 100 to 200 units (1 to 2 injections per muscle). ● Pronator teres: 100 to 200 units (1 injection per muscle).			
	Lower limbs: ● Flexor digitorum longus: 130 to 200 units (1 to 2 injections per muscle). ● Flexor hallucis longus: 70 to 200 units (1 injection per muscle). ● Gastrocnemius, medial head: 100 to 150 units (1 injection per muscle). ● Gastrocnemius, lateral head: 100 to 150 units (1 injection per muscle). ● Soleus: 330 to 500 units (3 injections per muscle). ● Tibialis posterior: 200 to 300 units (2 injections per muscle).			
Spasticity of upper/lower	Upper Limb: 8 Units/kg to 16 Units/kg per limb		3 months	Maximum total dose per treatment session = 30 Units/kg or 1000

extremity (Pediatric, Children ≥2 years and Adolescents <18 years)	• Maximum total dose per treatment session = 16 Units/kg or 640 Units, whichever is lower			Units, whichever is lower
	Lower Limb: 10 Units/kg to 15 Units/kg per limb • Maximum total dose per treatment session for unilateral limb injections = 15 Units/kg or 1000 Units, whichever is lower • Maximum total dose per treatment session for bilateral limb injections = 30 Units/kg or 1000 Units, whichever is lower			
	Upper extremity • Brachialis: 3 to 6 units/kg (up to 2 sites per muscle) • Brachioradialis: 1.5 to 3 units/kg (1 site per muscle) • Biceps brachii: 3 to 6 units/kg (up to 2 sites per muscle) • Flexor carpi radialis (FCR): 2 to 4 units/kg (up to 2 sites per muscle) • Flexor carpi ulnaris (FCU): 1.5 to 3 units/kg (1 site per muscle) • Flexor digitorum profundus (FDP): 1 to 2 units/kg (1 site per muscle) • Flexor digitorum superficialis (FDS): 1.5 to 3 units/kg (up to 4 sites per muscle) • Pronator quadratus: 0.5 to 1 units/kg (1 site per muscle) • Pronator teres: 1 to 2 units/kg (1 site per muscle) Total dose: 8 to 16 units/kg not to exceed 640 units			
	Lower extremity: • Gastrocnemius: 6 to 9 units/kg (1 to 4 sites per muscle) • Soleus: 4 to 6 units/kg (1 to 2 sites per muscle) Total: 10 to 15 units/kg divided across both muscles (1 to 6 sites per muscle)			
Upper extremity focal dystonia	15-150 units	15-150 units	3 months	Total dose should be injected across affected muscles
Myobloc (rimabotulinumtoxinB)				
Indication	**Initial dose**	**Subsequent Dose**	**Retreatment**	**Additional Considerations**
Cervical dystonia	2,500 to 5,000 units divided among		3-4 months	Toxin treatment-naive patients: Use

	the affected muscles in patients previously treated with botulinum toxin; initial dose in previously untreated patients should be lower.		a lower initial dose.
Sialorrhea	1,500 to 3,500 units divided among the parotid (500 to 1,500 units/gland) and submandibular (250 units/gland) glands (1 injection per side of face)	4-6 months	Injection should be into parotid and/or submandibular gland

Xeomin (incobotulinumtoxinA)

Indication	Initial dose	Subsequent Dose	Retreatment	Additional Considerations
Blepharospasm or hemifacial spasm	25 units per eye (50 units per treatment session)	maximum dose: 50 units per eye (100 units per treatment session)	3 months	
Cervical dystonia	120 units	120-400 units	3 months	Maximum cumulative dose per treatment session: 400 units. Initial doses >120 units not shown to provide additional efficacy and may be associated with increased incidence of adverse effects.
Sialorrhea	100 units divided among the parotid (30 units/gland) and submandibular (20 units/gland) glands on both sides (ie, 4 injection sites per treatment session)		4 months	divide dose with a ratio of 3:2 between parotid and submandibular glands.
Spasticity of the upper limb	See the below table for dose range for specific muscle group and maximum dose.		3 months	Maximum cumulative dose per treatment session: 400 units.

Dosing of IncobotulinumtoxinA for Upper Limb Spasticity in Adults

Clinical Pattern/Muscle	Recommended Dose per Muscle	Recommended No. of Injection Sites per Muscle
Clenched fist; flexor digitorum superficialis	25–100 units	2 sites

Clenched fist; flexor digitorum profundus	25–100 units	2 sites
Flexed wrist; flexor carpi radialis	25–100 units	1-2 sites
Flexed wrist; flexor carpi ulnaris	20–100 units	1-2 sites
Flexed elbow; brachioradialis	25–100 units	1-3 sites
Flexed elbow; biceps	50–200 units	1-4 sites
Flexed elbow; brachialis	25–100 units	1-2 sites
Pronated forearm; pronator quadratus	10–50 units	1 site
Pronated forearm; pronator teres	25–75 units	1-2 sites
Thumb-in-palm; flexor pollicis longus	10–50 units	1 site
Thumb-in-palm; adductor pollicis	5–30 units	1 site
Thumb-in-palm; flexor pollicis brevis/opponens pollicis	5–30 units	1 site

Dosing of IncobotulinumtoxinA for Upper Limb Spasticity in Children ≥2 years and Adolescents ≤17 years

NOTE: If a single upper extremity being treated, the total dose should not exceed 8 units/kg divided among affected muscles up to a maximum of 200 units per single upper limb; if both upper limbs are treated, total dose should not exceed 16 units/kg up to a maximum of 400 units.

Muscle	Dosage Range	Maximum Dose (units)	Number of Injection Sites Per Muscle
Adductor pollicis	0.5 units/kg	12.5	1
Biceps	2 to 3 units/kg	75	1 to 3
Brachialis	1 to 2 units/kg	50	1 to 2
Brachioradialis	1 to 2 units/kg	50	1 to 2
Flexor carpi radialis	1 unit/kg	25	1

Flexor carpi ulnaris	1 unit/kg	25	1
Flexor digitorum profundus	1 unit/kg	25	1
Flexor digitorum superficialis	1 unit/kg	25	1
Flexor pollicis brevis/Opponens pollicis	0.5 unit/kg	12.5	1
Flexor pollicis longus	1 unit/kg	25	1
Pronator quadratus	0.5 units/kg	12.5	1
Pronator teres	1 to 2 units/kg	50	1 to 2

Daxxify (daxibotulinumtoxinA-lanm)				
Indication	**Initial dose**	**Subsequent Dose**	**Retreatment**	**Additional Considerations**
Cervical dystonia	125 to 250 units divided among affected muscles		3 months	Total recommended dosage for a single treatment session: 125 to 250 units. Dose and number of injection sites should be personalized considering previous treatment, response, duration of effect, and any adverse events. The dosage can be modified by increments of 50 to 75 units depending on the individual's response.

Experimental or Investigational / Not Medically Necessary

1. **All botulinum toxin preparations (regardless of type)** are considered contraindicated, experimental, investigational, or unproven in the following cases:
    a. Infection at the proposed injection site***; or***
    b. Known hypersensitivity to any botulinum toxin preparation or the components in the formulation***; or***
    c. Retreatment of a condition with the same or different agent after a failed initial trial, regardless of if the member continues to meet clinical criteria***; or***

NOTE: If the member initially failed therapy due to an agent-specific intolerance or reaction, rather than a clinical feature, then this statement may not apply.

2. The Plan deems the use of botulinum toxin for **ALL** cosmetic purposes as not medically necessary. Such cosmetic purposes include, but are not limited to:
    a. chin dimpling; ***or***
    b. eyebrow elevation/shaping ("brow lift"); ***or***
    c. flaring nostrils (nasal flare); ***or***
    d. forehead lines; ***or***
    e. glabellar facial ("frown") lines; ***or***
    f. labiomandibular grooves; ***or***
    g. lateral brow lift; ***or***
    h. lateral canthal lines ("crow's feet"); ***or***
    i. lip lines; ***or***
    j. radial lines on the dorsum of the nose (bunny lines); ***or***
    k. to treat prominent platysma muscle bands (age-related neck degeneration).
3. **Botulinum toxin antibody assays** are considered experimental or investigational and are therefore not covered by the Plan.

<u>OnabotulinumtoxinA (Botox) (J0585)</u>

The use of OnabotulinumtoxinA (Botox) for any other indication not listed above is considered experimental, investigational, or unproven; these excluded indications include, but are not limited to, the following:

A. Acute and chronic back pain
B. Acute and chronic shoulder pain
C. Anal sphincter achalasia
    a. *Rationale:* A 2012 meta-analysis on 16 nonrandomized studies examining Botox for internal anal sphincter achalasia revealed significantly higher rates of non-response and adverse outcomes when compared to myectomy. Further evidence is required to determine a potential benefit of Botox therapy in this patient population.
D. benign prostatic hyperplasia (BPH, benign prostatic hypertrophy) with lower urinary tract symptoms (LUTS)
    a. *Rationale:* There is insufficient evidence to support the use of OnabotulinumtoxinA for men with lower urinary tract symptoms caused by benign prostatic hyperplasia. Currently, no guidelines in the field endorse OnabotulinumtoxinA as a potential treatment option. To fully evaluate the short- and long-term efficacy, including the need for repeated injections in patients with LUTS due to BPH, large-scale, placebo-controlled

randomized trials are necessary. Furthermore, given the availability of several effective treatments for BPH, the potential role of BoNT-A should be examined in further randomized trials that compare it to **α**-blockers, 5-**α** reductase inhibitors, minimally invasive treatments, and even traditional surgery.

E. Carpal tunnel syndrome
F. Chronic idiopathic constipation (CIC)
G. Chronic migraine prophylaxis, for the use of OnabotulinumtoxinA (Botox) in combination with calcitonin gene-related peptide (CGRP) monoclonal antibodies for the prevention of migraine: the Plan considers this approach experimental and investigational. While recent studies have shown potential benefits of this combination therapy in patients with difficult-to-treat chronic migraine, more research is needed to establish the long-term safety and efficacy of this approach.
H. Chronic pain, including, but not limited to: myofascial pain syndrome, inflammatory pain, knee osteoarthritis, musculoskeletal pain (including acute shoulder and back pain), neuropathic pain, postoperative pain, post-herpetic neuralgia, gynecologic pain syndromes, fibromyalgia.
    a. *Rationale:* Multiple systematic reviews and meta-analyses have concluded that the current evidence is inadequate to support the use of Botox in chronic pain syndromes.
I. Chronic paralytic strabismus, except when used in conjunction with surgical repair to reduce ocular antagonist muscle contracture.
J. Club foot (e.g. talipes equinovarus)
    a. *Rationale:* The existing evidence consists of a small (n=20) randomized trial showing no benefit with Botox in reducing cast time, need for further procedural intervention, or risk for relapse. A separate, larger study with 239 patients found some evidence of efficacy for Botox, however the study was designed as a retrospective case series. Further randomized, prospective evidence is needed to determine a potential benefit of Botox for this indication.
K. Cosmetic strabismus, defined as adults with congenital strabismus without binocular fusion.
L. Depression
M. First-bite syndrome, with or without pain that has failed traditional analgesics
N. Frey Syndrome (i.e. Gustatory sweating)
    a. *Rationale:* A 2013 evidence-based review concluded that the lack of randomized clinical evidence for Botox in Frey's syndrome limits the support for clinical use.
O. Gastroparesis
    a. *Rationale:* There is limited evidence to support the use of OnabotulinumtoxinA for gastroparesis. Some small studies have suggested potential benefit in reducing symptoms and improving gastric emptying, but larger randomized controlled trials are

needed to further evaluate its efficacy and safety for this condition. Therefore, more research is needed before making a definitive conclusion about the effectiveness of OnabotulinumtoxinA for gastroparesis.

P. Hyperhidrosis of the face/neck
    a. *Rationale:* more high-quality studies are needed to further evaluate the safety and efficacy of Botox in the treatment of craniofacial hyperhidrosis.

Q. Migraines or other headaches (e.g. tension, cluster, chronic daily) that do not meet the above criteria
    a. *Rationale:* OnabotulinumtoxinA has been used with varying degrees of success in a small number of patients suffering from headaches other than chronic migraine, including post-whiplash (cervicogenic) headache, tension-type headache, and cluster headache. The manufacturer cautions that the safety and effectiveness of onabotulinumtoxinA for prophylaxis of episodic migraine (less than or equal to 14 headache days per month) have not been established. The American Academy of Neurology (AAN) does not endorse the use of onabotulinumtoxinA as a treatment for headaches other than chronic migraine.

R. Motor tics / Tourette Syndrome
    a. *Rationale:*
        i. The American Academy of Neurology provides level C rating in 2019 practice guideline for prescribing botulinum toxin injections for the treatment of adolescents and adults with localized and bothersome simple motor tics when the benefits of treatment outweigh the risks. Furthermore, AAN provide level C rating for prescribing botulinum toxin injections for the treatment of older adolescents and adults with severely disabling or aggressive vocal tics when the benefits of treatment outweigh the risks. Therefore, Botox for Tourette Syndrome will be considered experimental or investigational.
        ii. A 2018 Cochrane Database analysis looked at the use of Botox in the treatment of motor tics. They found only a single randomized trial that met their selection criteria, and only 20 patients enrolled in the study, and that the quality of the evidence was "low-quality". In conclusion, the authors stated that they were "uncertain about botulinum toxin effects in the treatment of focal motor and phonic tics in select cases, as we assessed the quality of the evidence as very low. Additional randomised controlled studies are needed to demonstrate the benefits and harms of botulinum toxin therapy for the treatment of motor and phonic tics in patients with Tourette's syndrome."

S. Obesity

T. Painful bruxism
U. Palatal myoclonus
V. Phonic tics
W. Plantar fasciitis
X. Postnatal brachial plexus injury
Y. Post-radiation myokymia, including facial myokymia and trismus
Z. Raynaud's Phenomenon
    a. *Rationale*: Limited studies, including small non-controlled trials, case series, and retrospective reviews, have suggested some potential benefits of using onabotulinumtoxinA (botulinum toxin A) for severe symptoms associated with primary or secondary Raynaud phenomenon (RP). While a small randomized, double-blind, placebo-controlled trial in patients with scleroderma-associated RP also showed some positive effect in patient-reported clinical measures, it did not demonstrate significant improvements in blood flow as measured by laser Doppler imaging, which was the primary outcome. A systemic review found insufficient evidence to assess the efficacy of onabotulinumtoxinA in severe RP, and experts recommend reserving its use for patients who have not tolerated or have failed initial conventional therapy. Further trials may be necessary to determine the role of onabotulinumtoxinA in this condition.
AA. Refractory interstitial cystitis
BB. Tardive dyskinesia: Small noncontrolled trials suggest that botulinum toxin A may be beneficial for treating localized tardive dyskinesia, such as orofacial, head and neck, and cervical symptoms. However, the evaluation of the data is limited due to several studies not specifying the type of botulinum toxin A product used. Case reports primarily evaluating onabotulinumtoxinA have demonstrated benefits in most patients. However, the American Academy of Neurology clinical practice guidelines consider the data inadequate to support or refute the use of botulinum toxin type A for treating tardive dyskinesia.
CC. Temporomandibular Disorders (TMD): There is limited evidence supporting the use of botulinum toxin A (BTX-A) for the treatment of Temporomandibular Disorders (TMD). Some small randomized controlled trials and case reports have suggested that BTX-A injections may provide pain relief and improve jaw function in patients with TMD. However, the evidence is not conclusive and larger, more rigorous studies are needed to determine the effectiveness and safety of BTX-A in the treatment of TMD.
DD. Thoracic outlet syndrome
EE. Trigeminal neuralgia

a. *Rationale:* The current evidence is either uncontrolled or nonrandomized with small patient samples. Review articles have suggested there may be some efficacy for Botox in trigeminal neuralgia but indicate that further study is needed.

FF. Upper esophageal sphincter dysfunction

AbobotulinumtoxinA (Dysport) (J0586)

The use of AbobotulinumtoxinA (Dysport) for any other indication not listed above is considered experimental, investigational, or unproven; these excluded indications include, but are not limited to, the following:

A. AbobotulinumtoxinA (Dysport) is contraindicated in members with allergy to cow's milk protein, per FDA guidelines
B. Achalasia or upper esophageal sphincter dysfunction
C. Benign prostatic hypertrophy (BPH)
    a. *Rationale:* A 2011 review article on abobotulinumtoxinA for lower urinary tract symptoms related to BPH concluded that the level of evidence is low and further randomized controlled trials are necessary.
D. Carpal tunnel syndrome
E. Charcot-Marie-Tooth disease
F. Chronic musculoskeletal and myofascial pain
    a. *Rationale:* A systematic review of the available randomized trials found lack of efficacy for Dysport in myofascial pain syndromes.
G. Gastroparesis
    a. *Rationale:* There is currently insufficient evidence to support the use of AbobotulinumtoxinA (Dysport) for gastroparesis. While botulinum toxin type A has been studied in the treatment of gastroparesis, most studies have focused on the use of onabotulinumtoxinA (Botox) and there is limited research on the efficacy of abobotulinumtoxinA for this indication. More research is needed to determine the safety and effectiveness of abobotulinumtoxinA in the treatment of gastroparesis.
H. Headaches, including migraines, tension headaches, or headaches secondary to cranial neuralgia
    a. *Rationale:* A prospective, multi-center, randomized, double-blind placebo-controlled trial found no significant difference between placebo and Dysport in headache free days (primary outcome) among patients suffering from chronic migraine.[5-6]
I. Hyperhidrosis, other than axillary hyperhidrosis

a. *Rationale:* An expert review by the American Academy of Neurology concluded that the evidence for Dysport in palmar hyperhidrosis was inadequate to guide clinical decision making.

J. Lateral epicondylitis
K. Obesity
L. Plantar fasciitis
M. Postnatal brachial plexus injury
N. Raynaud's Phenomenon
    a. *Rationale*: There is limited evidence to support the use of Dysport (abobotulinumtoxinA) in the treatment of Raynaud's Phenomenon (RP). Some small studies and case reports have suggested that botulinum toxin A (BTX-A) injections, including Dysport, may have some benefit for the treatment of severe RP symptoms. However, the evidence is not yet strong enough to make definitive recommendations for the use of Dysport in RP treatment. More studies are needed to determine the optimal dose, injection sites, and duration of effect for BTX-A in the treatment of RP.
O. Refractory interstitial cystitis
P. Shoulder pain
Q. Strabismus
R. Tardive dyskinesia
    a. Rationale: AAN clinical practice guidelines consider the data insufficient to support or refute the use of botulinum toxin type A for treating tardive dyskinesia.
S. Temporomandibular Disorders (TMD)
    a. Rationale: There is limited evidence to support the use of Dysport (abobotulinumtoxinA) in the treatment of Temporomandibular Disorders (TMD). Some small studies and case reports have suggested that botulinum toxin A (BTX-A) injections, including Dysport, may have some benefit for the treatment of certain types of TMD, however, the evidence is not yet strong enough to make definitive recommendations for the use of Dysport in TMD treatment. More studies are needed to determine the optimal dose, injection sites, and duration of effect for BTX-A in the treatment of TMD.
T. Tourette Syndrome
    a. *Rationale:* There is currently insufficient evidence to support the use of Dysport (abobotulinumtoxinA) in the treatment of Tourette Syndrome. While some small studies and case reports have shown promise, larger, well-designed clinical trials are needed to fully evaluate the safety and efficacy of this treatment approach. The American Academy of Neurology's clinical practice guidelines currently do not recommend the use of botulinum toxin for the treatment of tics in Tourette Syndrome.

U. Trigeminal neuralgia

RimabotulinumtoxinB (Myobloc) (J0587)

The use of RimabotulinumtoxinB (Myobloc) for any other indication not listed above is considered experimental, investigational, or unproven; these excluded indications include, but are not limited to, the following:

A. Bladder dysfunction (e.g. overactive bladder, detrusor hyperreflexia)
    a. *Rationale:* The evidence has been contradictory or inconclusive, with some studies showing RimabotulinumtoxinB efficacy while others have demonstrated a lack of benefit. A 2011 Cochrane review (updating the previous 2007 review) identified 19 studies meeting inclusion criteria, and found that the efficacy of RimabotulinumtoxinB was inferior to that of type A toxins with a substantially shorter duration of benefit across randomized trials for bladder dysfunction.
B. Blepharospasm and Associated Facial Nerve Disorders (e.g., hemifacial spasm)
    a. *Rationale:* RimabotulinumtoxinB is limited in efficacy and experience, but has been used for blepharospasm or hemifacial spasm, mainly in patients who have responded to onabotulinumtoxinA. The American Academy of Neurology recommends onabotulinumtoxinA and incobotulinumtoxinA as treatment options, and abobotulinumtoxinA may be considered for blepharospasm, but does not make a recommendation for rimabotulinumtoxinB due to insufficient data.
C. Disabling headaches (e.g., migraine, cluster headache)
D. Gastroparesis
    a. *Rationale:* There is limited evidence to support the use of RimabotulinumtoxinB (Myobloc) in the treatment of gastroparesis. Some small studies have suggested potential benefit in improving symptoms such as nausea and vomiting, but more research is needed to establish the safety and effectiveness of this treatment for gastroparesis.
E. Hyperhidrosis (including primary axillary hyperhidrosis and focal palmar hyperhidrosis)
    a. *Rationale:* Although RimabotulinumtoxinB has been utilized for symptomatic management of primary axillary and focal palmar hyperhidrosis characterized by excessive glandular secretion, its efficacy evidence and experience are less extensive when compared to OnabotulinumtoxinA.
F. Incontinence after spinal cord injury
G. Involuntary (smooth) muscle overactivity (e.g., neurogenic voiding dysfunction, anal sphincter disorders)

H. Musculoskeletal pain disorders (e.g., myofascial pain syndrome, chronic low back pain, pain associated with brachial plexopathy)

I. Raynaud's Phenomenon

    a. *Rationale*: There is currently insufficient evidence to support the use of RimabotulinumtoxinB (Myobloc) in the treatment of Raynaud's Phenomenon.

J. Spasmodic dysphonia

K. Spasticity in adults, including post-stroke spasticity and spasticity of the upper and/or lower extremities associated with other neurological disorders

    a. *Rationale:* The clinical evidence for RimabotulinumtoxinB (type b agent) is substantially limited compared to type A agents. A single randomized trial on 24 patients showed possible improvements with RimabotulinumtoxinB but concluded that larger studies with long-term follow up were needed for further evidence. The US Pharmacopeial Convention has stated that off-label use of RimabotulinumtoxinB for spasticity secondary to stroke or brain injury may be indicated, however updated data has failed to demonstrated the statistically significant benefit seen in earlier studies. The American Academy of Neurology currently states (per 2016 guidelines), that the data is insufficient to determine the efficacy of Myobloc in lower limb spasticity, and the evidence is limited to a single Class I study for upper limb spasticity.

L. Spasticity in children with cerebral palsy (CP)

    a. *Rationale:* A review by the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society concluded that the evidence was limited in children with CP, and that the existing evidence on RimabotulinumtoxinB showed inferior efficacy compared to type A toxins.

M. Temporomandibular Disorders (TMD)

    a. Rationale: There is currently insufficient evidence to support the use of RimabotulinumtoxinB (Myobloc) in the treatment of Temporomandibular Disorders (TMD). While there are some studies investigating the use of botulinum toxin in TMD, the evidence is limited and conflicting, with some studies reporting positive outcomes and others reporting no significant benefit. Further research is needed to determine the efficacy of RimabotulinumtoxinB in the treatment of TMD.

N. Tourette Syndrome

    a. *Rationale:* There is currently limited evidence on the use of RimabotulinumtoxinB (Myobloc) in the treatment of Tourette Syndrome. While some small studies have shown potential benefit, further research is needed to determine its efficacy and safety for this indication.

O. Upper esophageal dysfunction or achalasia

a. *Rationale:* A 2014 Cochrane review revealed no randomized clinical trials on RimabotulinumtoxinB for upper esophageal dysfunction.

<u>IncobotulinumtoxinA (Xeomin) (J0588)</u>

The use of IncobotulinumtoxinA (Xeomin) for any other indication not listed above is considered experimental, investigational, or unproven; these excluded indications include, but are not limited to, the following:

A. Atrial fibrillation
B. Detrusor hyperactivity (e.g. bladder overactivity)
    a. *Rationale:* There is limited evidence on Xeomin in patients with overactive bladder. Preliminary results on 95 patients from a double-blinded study on Xeomin and Botox in bladder overactivity were presented at the 27th Annual Congress of the European Association of Urology. However, further peer-reviewed randomized evidence is currently lacking, limiting guidance for clinical application.
C. Hyperhidrosis, including axillary, palmar, and craniofacial
    a. *Rationale:* Xeomin and Botox were compared in a double-blind trial in treating palmar hyperhidrosis. There were no significant differences in short- or long-term efficacy outcomes, however only 25 patients were included in the study. Given the small sample size and lack of confirmatory studies, further evidence is required. Similar limitations are present in comparable studies on axillary hyperhidrosis. Further evidence is needed to determine a potential benefit of Xeomin for this indication.
D. Gastroparesis
    a. *Rationale:* There is currently insufficient evidence to support the use of IncobotulinumtoxinA (Xeomin) for gastroparesis. While some small studies have shown promising results, larger randomized controlled trials are needed to establish its efficacy and safety in this condition. The use of botulinum toxin for gastroparesis is still considered investigational and not recommended for routine clinical use.
E. Migraine prophylaxis
    a. *Rationale:* The evidence for Xeomin in migraine prophylaxis comes from small, retrospective case series and poster presentations, indicating further prospective, randomized evidence is required to guide any potential clinical application.
F. Parkinson disease with tremor
    a. Rationale: There is insufficient, conflicting, or poor evidence regarding the use of incobotulinumtoxinA for Parkinson disease with tremor, and more research is needed.
G. Plantar fasciitis
    a. Rationale: There is a lack of sufficient, conflicting, or poor evidence regarding the use of incobotulinumtoxinA for plantar fasciitis.
H. Post-stroke lower limb spasticity

a. *Rationale:* A prospective, open label study on 71 patients demonstrated safety and efficacy of Xeomin in post-stroke lower limb spasticity, however further randomized studies are required to establish clinical use. Furthermore, the 2016 American Academy of Neurology Guidelines state that there "is insufficient evidence to support or refute the use of incoBoNT-A for the treatment of lower limb spasticity."

I. Raynaud's Phenomenon
   a. *Rationale*: There is currently insufficient evidence to support the use of IncobotulinumtoxinA (Xeomin) for Raynaud's Phenomenon.

J. Temporomandibular Disorders (TMD)
   a. *Rationale:* There is limited evidence to support the use of IncobotulinumtoxinA for the treatment of Temporomandibular Disorders (TMD). While some studies have shown potential benefits, more research is needed to establish its efficacy and safety in this context.

K. Tourette Syndrome
   a. *Rationale:* There is insufficient evidence to support the use of IncobotulinumtoxinA (Xeomin) for Tourette Syndrome.

DaxibotulinumtoxinA-lanm (Daxxify) (J0589)

The use of DaxibotulinumtoxinA-lanm (Daxxify) for any other indication not listed above is considered experimental, investigational, or unproven; these excluded indications include, but are not limited to, the following:

A. Pancreatic Carcinoma
B. Plantar fascial fibromatosis
C. Spasmodic Dysphonia

Applicable Billing Codes (CPT/HCPCS/ICD-10 Codes)

Codes considered medically necessary if clinical criteria are met:

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
J0585	Injection, onabotulinumtoxinA, 1 unit (Botox®)
J0586	Injection, abobotulinumtoxinA, 5 units (Dysport®)
J0587	Injection, rimabotulinumtoxinB, 100 units (Myobloc®)

J0588	Injection, incobotulinumtoxinA, 1 unit (Xeomin®)
C9160*	Daxxify (daxibotulinumtoxinA-lanm) Injection, daxibotulinumtoxina-lanm, 1 unit **Code Note: Code will be deleted effective 3/31/24 - see J0589*
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit (Daxxify®)
ICD-10 codes considered medically necessary if criteria are met for onabotulinumtoxinA (J0585):	
G04.1	Tropical spastic paraplegia
G11.4	Hereditary spastic paraplegia
G12.21	Amyotrophic lateral sclerosis
G20	Parkinson's disease
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G24.8	Other dystonia
G25.0	Essential tremor
G35	Multiple sclerosis
G36.0	Neuromyelitis optica
G36.1	Acute and subacute hemorrhagic leukoencephalitis
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
G37.81	Myelin oligodendrocyte glycoprotein antibody disease
G37.89	Other specified demyelinating diseases of central nervous system
G37.9	Demyelinating disease of central nervous system, unspecified

G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable with status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G51.0	Bell's palsy
G51.1	Geniculate ganglionitis
G52.2	Melkersson's syndrome
G51.3	Clonic hemifacial spasm
G51.31	Clonic hemifacial spasm, right
G51.32	Clonic hemifacial spasm, left
G51.33	Clonic hemifacial spasm, bilateral
G51.39	Clonic hemifacial spasm, unspecified
G51.54	Facial myokymia
G51.58	Other disorders of facial nerve
G51.9	Disorder of facial nerve, unspecified
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic 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
G82.84	Quadriplegia, C5-C7 incomplete
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
G83.31	Monoplegia, unspecified affecting right dominant side
G83.32	Monoplegia, unspecified affecting left dominant side
G83.33	Monoplegia, unspecified affecting right nondominant side
G83.34	Monoplegia, unspecified affecting left nondominant side
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
H50.21	Vertical strabismus, right eye
H50.22	Vertical strabismus, left eye
H50.60	Mechanical strabismus, unspecified
H50.69	Other mechanical strabismus
H50.89	Other specified strabismus
H50.9	Unspecified strabismus
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
I69.041	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
I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant 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
I69.131	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
I69.141	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.142	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side

I69.143	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.144	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.149	Monoplegia of lower 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
I69.231	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
I69.241	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.242	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.243	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.244	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhageaffecting 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
I69.331	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
I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
I69.344	Monoplegia of lower limb following cerebral infarction affecting left non-dominant 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
I69.831	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
I69.841	Monoplegia of lower limb following other cerebrovascular disease affecting right dominant side
I69.842	Monoplegia of lower limb following other cerebrovascular disease affecting left dominant side
I69.843	Monoplegia of lower limb following other cerebrovascular disease affecting right non-dominant side
I69.844	Monoplegia of lower limb following other cerebrovascular disease affecting left non- dominant side
I69.849	Monoplegia of lower 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
I69.941	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side
I69.942	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side
I69.943	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.944	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.949	Monoplegia of lower 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
J38.5	Laryngeal spasm
K11.7	Disturbances of salivary secretion
K22.0	Achalasia of cardia
K60.1	Chronic anal fissure
K60.2	Anal fissure, unspecified
L74.510	Primary focal hyperhidrosis, axilla

L74.512	Primary focal hyperhidrosis, palms
L98.8	Other specified disorders of the skin and subcutaneous tissue
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 [bladder sphincter dyssynergy] [due to spinal cord injury, bladder-hyphensphincter dyssynergia]
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
N39.491	Coital incontinence
N39.492	Postural (urinary) incontinence
N39.498	Other specified urinary incontinence
R13.10	Dysphagia, unspecified
R13.11	Dysphagia, oral phase
R13.12	Dysphagia, oropharyngeal phase
R13.13	Dysphagia, pharyngeal phase
R13.14	Dysphagia, pharynoesophageal phase
R13.19	Other dysphagia
R25.2	Cramp and spasm
R32	Unspecified urinary incontinence
R39.81	Functional urinary incontinence
R49.0	Dysphonia
R61	Generalized hyperhidrosis
ICD-10 codes considered medically necessary if criteria are met for abobotulinumtoxinA (J0586) :	
G11.4	Hereditary spastic paraplegia
G24.3	Spasmodic torticollis
G24.5	Blepharospasm
G24.8	Other dystonia

G35	Multiple sclerosis
G36.0	Neuromyelitis optica
G36.1	Acute and subacute hemorrhagic leukoencephalitis
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
G37.81	Myelin oligodendrocyte glycoprotein antibody disease
G37.89	Other specified demyelinating diseases of central nervous system
G37.9	Demyelinating disease of central nervous system, unspecified
G51.3	Clonic hemifacial spasm
G51.31	Clonic hemifacial spasm, right
G51.32	Clonic hemifacial spasm, left
G51.33	Clonic hemifacial spasm, bilateral
G51.39	Clonic hemifacial spasm, unspecified
G51.8	Other disorders of facial nerve
G51.9	Disorder of facial nerve, unspecified
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
G81.10	Spastic hemiplegia affecting unspecified sideSpastic hemiplegia
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
G82.84	Quadriplegia, C5-C7 incomplete
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
G83.30	Monoplegia, unspecified affecting unspecified side
G83.31	Monoplegia, unspecified affecting right dominant side
G83.32	Monoplegia, unspecified affecting left dominant side
G83.33	Monoplegia, unspecified affecting right nondominant side
G83.34	Monoplegia, unspecified affecting left nondominant side
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

I69.041	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
I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant 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
I69.0541	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant sideHemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage
I69.059	Hemiplegia and hemiparesis 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
I69.141	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.142	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.143	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side

I69.144	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.098	Other sequelae following nontraumatic subarachnoid hemorrhage
I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant sideHemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage
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
I69.231	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
I69.241	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.242	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.243	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.244	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhageaffecting right dominant side

I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhageaffecting left dominant sideHemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage
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
I69.331	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
I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
I69.344	Monoplegia of lower limb following cerebral infarction affecting left non-dominant 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
I69.831	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
I69.841	Monoplegia of lower limb following other cerebrovascular disease affecting right dominant side
I69.842	Monoplegia of lower limb following other cerebrovascular disease affecting left dominant side
I69.843	Monoplegia of lower limb following other cerebrovascular disease affecting right non-dominant side
I69.844	Monoplegia of lower limb following other cerebrovascular disease affecting left non- dominant side
I69.849	Monoplegia of lower limb following other cerebrovascular disease affecting unspecified side
I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant sideHemiplegia and hemiparesis following other cerebrovascular disease
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
I69.931	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
I69.941	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side
I69.942	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side
I69.943	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.944	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease affecting unspecified side
I69.951	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant sideHemiplegia and hemiparesis following unspecified cerebrovascular disease
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
H49.9	Unspecified paralytic strabismus
K11.7	Disturbances of salivary secretion
K60.0	Acute anal fissure
K60.1	Chronic anal fissure
K60.2	Anal fissure, unspecified
L74.510	Primary focal hyperhidrosis, axilla
L98.8	Other specified disorders of the skin and subcutaneous tissue
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
M62.831	Muscle spasm of calf
M62.838	Other muscle spasm
R25.2	Cramp and spasm
ICD-10 codes considered medically necessary if criteria are met for rimabotulinumtoxinB (J0587):	
G12.21	Amyotrophic lateral sclerosis
G20	Parkinson's disease
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.8	Other dystonia
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified

K11.7	Disturbances of salivary secretion
R25.2	Cramp and spasm
ICD-10 codes considered medically necessary if criteria are met for incobotulinumtoxinA (J0588):	
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G51.3	Clonic hemifacial spasm
G51.8	Other disorders of facial nerve
G51.9	Disorder of facial nerve, unspecified
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G81.10	Spastic hemiplegia affecting unspecified sideSpastic hemiplegia
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
G82.53	Quadriplegia, C5-C7 complete
G82.84	Quadriplegia, C5-C7 incomplete
G83.0	Diplegia of upper limbs
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
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
I69.052	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
I69.0541	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant sideHemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage
I69.059	Hemiplegia and hemiparesis 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 affectingright dominant sideHemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage
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
I69.231	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 hemorrhageaffecting right dominant side
I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant sideHemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage
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
I69.331	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
I69.831	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 sideHemiplegia and hemiparesis following other cerebrovascular disease
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
I69.931	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 sideHemiplegia and hemiparesis following unspecified cerebrovascular disease
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

K11.7	Disturbances of salivary secretion
L98.8	Other specified disorders of the skin and subcutaneous tissue
M62.40	Contracture of muscle, unspecified siteContracture of muscle
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
ICD-10 codes considered medically necessary if criteria are met for daxibotulinumtoxinA-lanm (Daxxify) (J0589):	
G24.3	Spasmodic torticollis
L98.8	Other specified disorders of the skin and subcutaneous tissue

CPT/HCPCS Codes considered medically necessary but may be subject to medical necessity review:

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
31573	Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43253	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
46505	Chemodenervation of internal anal sphincter [covered for anal fissure only]
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64612	Chemodenervation of muscles(s); muscles(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) (e.g., scalp, face, neck), per day
67345	Chemodenervation of extraocular muscle
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
95873	Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)
95874	Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)
S2340	Chemodenervation of abductor muscle(s) of vocal cord
S2341	Chemodenervation of adductor muscle(s) of vocal cord

CPT/HCPCS codes considered experimental or investigational or *not* considered medically necessary

Code	*Description*
86609	Antibody; bacterium, not elsewhere specified [neutralizing antibodies to botulinum toxin]

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IncobotulinumtoxinA (Xeomin)

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