Reference number(s)
2170-A

Jurisdiction Specific Medicare Part B Botulinum Toxins

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Botox	onabotulinumtoxinA
Daxxify	daxibotulinumtoxinA
Dysport	abobotulinumtoxinA
Xeomin	incobotulinumtoxinA
Myobloc	rimabotulinumtoxinB

Covered Uses[1,2]

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Achalasia
- Anal Fissure
- Blepharospasm
- Blepharospasm Associated with Orofacial Dystonia
- Cervical Dystonia
- Chronic Migraine
- Focal Hand Dystonia
- Hemifacial Spasm/Facial Dystonia
- Hyperhidrosis
- Laryngeal Dystonia (Spasmodic Dysphonia)
- Neurogenic Bladder

- Overactive Bladder (OAB)/Urinary Incontinence (UI)
- Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS)
- Sialorrhea
- Upper and Lower Spasticity
- Strabismus

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia and valid and documented reasons stating why the requested product is being requested for such indication.

Exclusions[1]

Coverage will not be provided for members with any of the following exclusions:

- The requested medication is being used for cosmetic purposes/cosmetic surgery.
- The requested medication is being used for an approved indication but also being used with cosmetic intent.
- Contraindication to botulinum toxin injection.
- The member has an existing medical condition which could affect the neuromuscular function.
- The member has hypersensitivity to any botulinum toxin injection preparation or to any of the components in the formulation of the serotype.
- The member is affected by severe clotting disorders.
- The member is affected by Infection at the injection site.
- The requested medication is being used for conscious sedation and monitored anesthesia care.
- Use of image guidance for the injection of botulinum toxin injection.

Documentation[1]

The following documentation must be available, upon request, for all submissions:

- Relevant medical history, physical examination and results of pertinent diagnostic tests or procedures.
- Documentation of medical necessity for the treatment. For spastic conditions other than upper or lower limb spasticity, blepharospasm, hemifacial spasm, cervical dystonia or other focal dystonias, documentation should include a statement that the spastic condition has been unresponsive to conventional treatment.
- Documentation of diagnosis.
- Dosage(s), site(s), and frequency of injection.
- Documentation of the medical necessity for associated electromyography when used.
- Description of the effectiveness of treatment.

Prescriber Specialties[1]

The healthcare professionals who perform botulinum injections/procedures for chronic pain (not surgical anesthesia) are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program whose core curriculum includes the performance and management of the procedures addressed in this policy. Credentialing or privileges are required for procedures performed in inpatient and outpatient settings.

Coverage Criteria[1-7]

Achalasia

Initial

Authorization of 1 month may be granted for treatment of achalasia when all of the following criteria are met:

- The member has objective documentation of the clinical features consistent with the diagnosis of achalasia.
- The member has chronic achalasia measured on an objective clinical scale at baseline with the same scale that will be used during each assessment (e.g., Eckert Scale).
- One of the following applies:
    - The member is medically high-risk and cannot undergo other invasive treatments (e.g., peroral endoscopic myotomy [POEM], Heller myotomy, pneumatic dilation [PD]).
    - The requested medication is being used as a bridge for those members awaiting more effective treatments (e.g. Heller myotomy, pneumatic dilations or POEM).
    - The member is undergoing work-up and treatment planning of definitive treatments.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The initial dose of the requested medication is between 80 and 100 units, not exceeding 100 units.
- The injection is not in the esophageal body.
- The member does not have either of the following:
    - Achalasia symptoms but insufficient manometric criteria to make the diagnosis.
    - A contraindication for upper endoscopy.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of achalasia when all of the following criteria are met:

- The member's chronic achalasia is measured on an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Eckert Scale).

- The member has documentation of informed clinical decisions regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent moderate to severe achalasia.
- There is evidence of a significant beneficial symptomatic response to the initial dose.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The subsequent dose of the requested medication is not above 100 units.
- The subsequent injection is given at least 30 days after the initial dose.
- The injection is not in the esophageal body.
- The member does not have either of the following:
    - Achalasia symptoms but insufficient manometric criteria to make the diagnosis.
    - A contraindication for upper endoscopy.

Anal Fissure

Initial

Authorization of 3 months may be granted for the treatment of anal fissure when all of the following criteria are met:

- The member has an anal fissure that has been present for more than 6 weeks.
- Conservative treatment has been tried for eliminating constipation and reducing anal sphincter spasm.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The dose of the requested medication is 20 units (10 units on each side of the fissure).

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of anal fissure when all of the following criteria are met:

- The member has documentation of informed clinical decision-making regarding repeated botulinum toxin injections and surgical treatment.
- The member has a reassessment of the symptoms and degree of persistent anal fissure.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The dose of the requested medication is up to 60 units.

Blepharospasm

Initial

Authorization of 3 months may be granted for the treatment of blepharospasm when all of the following criteria are met:

- The member has objective documentation of the clinical features consistent with the diagnosis of blepharospasm.
- The member has chronic blepharospasm of at least 30 days in duration measured using an objective clinical scale at baseline with the same scale that will be used during each assessment (e.g., Jankovic Rating Scale [JRS] and Blepharospasm Disability Index [BSDI]).
- The requested medication is an accepted first line treatment.

- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The initial dose of onabotulinumtoxinA (e.g., Botox) is 1.25-2.5 units into each of the 3 sites per affected facial or ocular muscle.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of blepharospasm when all of the following criteria are met:

- The member's chronic blepharospasm is measured on an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Jankovic Rating Scale [JRS] and Blepharospasm Disability Index [BSDI]).
- The member has documentation of informed clinical decisions regarding repeat botulinum toxin injections.
- The member has a reassessment of the severity and frequency of persistent blepharospasm.
- The member has persistent or reoccurrence of blepharospasm.
- The requested medication is onabotulinumtoxinA (e.g., Botox) and one of the following applies:
  - The initial treatment (1.25-2.5 units into each of the 3 sites per affected facial or ocular muscle) is considered sufficient and the administration of the same dose as initial is recommended.
  - The initial treatment is considered insufficient (defined as an effect which does not last longer than 2 months) and the administration of an increased dose is recommended, up to 5 units per site.
  - The initial treatment is not known or the member was not previously treated with onabotulinumtoxinA (e.g., Botox) and the dose is 1.25-2.5 units per injection site.
- The requested medication is incobotulinumtoxinA (e.g., Xeomin) and dose is based on the previous dosing with onabotulinumtoxinA.

Blepharospasm Associated with Orofacial Dystonia

Initial

Authorization of 3 months may be granted for the treatment of blepharospasm associated with orofacial dystonia when all of the following criteria are met:

- The member has objective documentation of the clinical features consistent with the diagnosis of blepharospasm associated with orofacial dystonia (e.g., eyelid spasms accompanied by jaw clenching or mouth opening, grimacing, and/or tongue movement).
- The member has moderate to severe chronic blepharospasm associated with orofacial dystonia measured by an objective clinical scale at baseline with the same scale that will be used during each assessment (e.g., Burke-Fahn-Marsden scale [BFMS], the Global Dystonia Severity Rating scale [GDRS], Craniocervical Dystonia Questionnaire, and the Jankovic Rating Scale [JRS]).
- The requested medication is an accepted first line treatment.
- The requested medication is onabotulinumtoxinA (e.g., Botox).

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of blepharospasm associated with orofacial dystonia when all of the following criteria are met:

- The member's moderate to severe chronic blepharospasm associated with orofacial dystonia is measured by an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Burke-Fahn-Marsden scale [BFMS], the Global Dystonia Severity Rating scale [GDRS], Craniocervical Dystonia Questionnaire, and the Jankovic Rating Scale [JRS]).
- The member has documentation of informed clinical decisions regarding repeat botulinum injections.
- The member has a reassessment of persistent blepharospasm associated with orofacial dystonia.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The number of injection sites and muscles injected is determined by the response to the initial injections.
- One of the following applies:
    - The initial treatment is considered sufficient, and administration of the same dose is recommended.
    - The initial treatment or subsequent treatments are considered insufficient (defined as an effect which does not last longer than 2 months) and administration of an increased dose is recommended.

Cervical Dystonia

Initial

Authorization of 3 months may be granted for the treatment of cervical dystonia when all of the following criteria are met:

- The member is not having multiple procedures (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) on the same day as botulinum toxin injection.
- The requested medication is not being used for generalized pain conditions (such as fibromyalgia), chronic nonspecific neck pain with or without cervical rotation, or chronic centralized pain syndromes, temporomandibular disorders with or without neck pain, severe bruxism with or without neck pain, myofascial pain syndrome, and cervical spondylosis with or without neck pain.
- The member has documentation which supports a diagnosis of cervical dystonia (CD).
- The etiology of the central nervous system impairment which is causing the CD is documented.
- The member has a history of recurrent clonic or tonic involuntary contractions of 1 or more of the following muscles:
    - Sternocleidomastoid
    - Splenius
    - Trapezius
    - Posterior cervical muscles

- The member has moderate to severe CD assessed by an objective scale at baseline with the same scale that will be used during each assessment (e.g., Tsui score and the Toronto Western Spasmodic Torticollis Rating Scale [TWSTRS]).
- The member has objective measurements of abnormal posturing, with limited range of motion in the neck, or sustained head tilt.
- The duration of the cervical dystonia is greater than 6 months.
- One of the following applies:
    - The requested medication is onabotulinumtoxinA (e.g., Botox) and the dose is based on the member's head and neck position, localization of pain, muscle hypertrophy, member response, and adverse event history with lower initial doses being used in botulinum toxin naïve members.
    - The requested medication is abobotulinumtoxinA (e.g., Dysport) and the dose is up to 500 Units given intramuscularly as a divided dose among the affected cervical muscles.
    - The requested medication is rimabotulinumtoxinB (e.g., Myobloc) and the dose is up to a total dosage of 2,500-5,000 Units divided among affected cervical muscles.
    - The requested medication is incobotulinumtoxinA (e.g., Xeomin) and the dose is up to 120 Units divided among affected cervical muscles per treatment session.
    - The requested medication is daxibotulinumtoxinA-lanm (e.g., Daxxify) and the dose is from 125-250 Units given intramuscularly as a divided dose among affected muscles.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of cervical dystonia when all of the following criteria are met:

- The member is not having multiple procedures (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) on the same day as botulinum toxin injection.
- The requested medication is not being used for generalized pain conditions (such as fibromyalgia), chronic nonspecific neck pain with or without cervical rotation, or chronic centralized pain syndromes, temporomandibular disorders with or without neck pain, severe bruxism with or without neck pain, myofascial pain syndrome, and cervical spondylosis with or without neck pain.
- The member's moderate to severe cervical dystonia is measured by an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Tsui score and the Toronto Western Spasmodic Torticollis Rating Scale [TWSTRS]).
- The member is requesting subsequent injections.
- The member's response to initial treatment is documented in the medical records.
- The member has a reassessment of clinical utility of the injection with documentation of informed clinical decision regarding repeat botulinum injections.
- The dose of the requested medication is of the following:
    - The requested medication is onabotulinumtoxinA (e.g., Botox) and the dose is based on the member's clinical response, head and neck position, localization of pain, and muscle hypertrophy.

- The requested medication is abobotulinumtoxinA (e.g., Dysport) and the doses are administered between 250 and 1000 Units to optimize clinical benefit and titrated in 250 Units in incremental steps according to member's response.
- The requested medication is rimabotulinumtoxinB (e.g., Myobloc) and the dose is up to a total dosage of 2,500 Units to 5,000 Units divided among effected cervical muscles.
- The requested medication is incobotulinumtoxinA (e.g., Xeomin) and the dose is 120 Units per treatment session.
- The requested medication is daxibotulinumtoxinA-lanm (e.g., Daxxify) and the dose is adjusted in 50 to 75 Unit increments according to the individual member's response with the total dose administered in a single treatment between 125-250 Units.

Chronic Migraine

Initial

Authorization of 3 months may be granted for the treatment of chronic migraine when all of the following criteria are met:

- The member is not having multiple procedures (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) on the same day as botulinum toxin injection.
- The requested medication is not being used for generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes, episodic migraine prophylaxis, temporomandibular disorders with or without headaches, tension headaches, severe bruxism with or without headaches, chronic daily headaches, myofascial pain syndrome with or without headaches and cervical spondylosis with or without headaches.
- The requested medication is onabotulinumtoxinA (e.g., Botox) or a botulinum toxin serotype that is approved by the FDA for chronic migraine prophylaxis.
- The dose is not above 195 units for onabotulinumtoxinA (e.g., Botox).
- The onabotulinumtoxinA (e.g., Botox) dose ranges from 155 to 195 units. The initial dose is 155 units given as 5 units per each site divided across 7 head/neck muscles (frontalis, corrugator, procerus, occipitalis, temporalis, trapezius, and cervical paraspinal muscle group).
- The requested medication is being used only for the indication of chronic migraine prophylaxis.
- The member has monthly headache days occurring greater than or equal to 15 headache days per month.
- The member has monthly migraine headache days occurring greater than or equal to 8 migraine headache days per month.
- The migraine headaches are documented to be lasting for a duration of greater than or equal to 4 hours on a migraine day.
- The chronic headaches have been present for a period of at least 3 months.
- The member has had a trial of and an inadequate response to a 2-month trial of at least 1 agent in any 2 of the following classes at the target dose of the usual effective dose or has a contraindication to the following medications or intolerance to 2 agents in each of the below classes:
    - Antidepressant class: amitriptyline, venlafaxine, nortriptyline, duloxetine
    - Beta blocker class: metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol

    - Calcium channel blocker class: verapamil
    - Antiepileptic class: valproate sodium, divalproex sodium, topiramate, gabapentin.
- If the member is also currently using a calcitonin gene-related peptide (CGRP) agent for chronic migraine prophylaxis and is going to be using the CGRP and botulinum toxin injection together, the following applies:
    - The member had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with CGRP use, but still has chronic migraines requiring additional therapy for chronic migraine prevention.
- The headaches are causing an objective significant functional disability.
- The headaches are moderate to severe in intensity with typical migraine headache characteristics.
- An objective assessment will be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale at each assessment.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of chronic migraine when all of the following criteria are met:

- The member is not having multiple procedures (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) on the same day as botulinum toxin injection.
- The requested medication is not being used for generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes, episodic migraine prophylaxis, temporomandibular disorders with or without headaches, tension headaches, severe bruxism with or without headaches, chronic daily headaches, myofascial pain syndrome with or without headaches and cervical spondylosis with or without headaches.
- The requested medication is onabotulinumtoxinA (e.g., Botox) or a botulinum toxin serotype that is approved by the FDA for chronic migraine prophylaxis.
- The dose is not above 195 units for onabotulinumtoxinA (e.g., Botox).
- The onabotulinumtoxinA (e.g., Botox) dose ranges between 155-195 Units to allow a discretionary 40 Units to be administered using a “follow-the-pain” strategy, resulting in 195 Units over 39 sites.
- The clinician(s) are aware and address the importance of cognitive-affective processes in headache disorders and address the potential for hypervigilance to bodily sensations and anxiety regarding the symptoms of headache pain when managing chronic migraine headaches.
- The number of total chronic migraine headache days have demonstrated a greater than or equal to 50% reduction in migraine headache days per month.
- The frequency of the total chronic migraine headache episodes has demonstrated greater than or equal to 50% reduction in migraine headache episodes per month.
- The member has a minimal important change (MIC) and a significant reduction of headache-related disability and objective improvement in functioning.
- Biobehavioral therapy (cognitive behavioral therapy, biofeedback, relaxation therapies, mindfulness-based therapies, acceptance and commitment therapy) has been assessed and implemented as appropriate for preventive and acute headache treatment.

- If the beneficiary is using concurrently with a CGRP agent for migraine prophylaxis, the beneficiary has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or the CGRP agent).

Focal Hand Dystonia

Initial

Authorization of 3 months may be granted for the treatment of Focal Hand Dystonia when all of the following criteria are met:

- The treatment consists of focal injections of the toxin into the muscles responsible for the abnormal postures.
- The member has objective documentation of the clinical features consistent with the diagnosis of Focal Hand Dystonia (FHD) at baseline with the same scale that will be used during each assessment (e.g. Fahn-Marsden rating scale, Unified Dystonia Rating Scale, Arm Dystonia Disability Scale [ADDS]; Tubiana-Chamagne Scale; and Writer's Cramp Rating Scale).
- The member has moderate to severe chronic Focal Hand Dystonia measured on an objective clinical scale.
- The injections are used with guidance either by ultrasound or by electromyography (EMG) with or without electrostimulation.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The specific pattern of dystonic postures and movements have been assessed to determine the appropriate dose depending on the site of muscle injection.
- Both of the following apply:
    - For injection(s) to the flexor muscles, the dose follows the following:
        - Flexor digitorum superficialis: 25-50 Units
        - Flexor pollicis longus: 5-20 Units
        - Flexor digitorum profundus: 20-60 Units
        - Flexor carpi radialis: 20-50 Units
        - Flexor carpi ulnaris: 15-60 Units
    - For injection(s) to the extensor muscles, the dose follows the following:
        - Extensor digitorum communis: 10-25 Units,
        - Extensor pollicis longus: 5-20 Units,
        - Extensor indicis: 5-10 Units,
        - Extensor carpi radialis longus: 5-20 Units,
        - Extensor carpi ulnaris: 5-20 Units

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Focal Hand Dystonia when all of the following criteria are met:

- The member's Focal Hand Dystonia (FHD) is measured by an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g. Fahn-Marsden rating scale, Unified Dystonia Rating Scale, Arm Dystonia Disability Scale [ADDS]; Tubiana-Chamagne Scale; and Writer's Cramp Rating Scale).

- The member has documentation of informed clinical decision regarding repeat botulinum injections.
- The member has had a reassessment of the degree of persistent Focal Hand Dystonia.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The specific pattern of dystonic postures and movements have been assessed to determine the appropriate dose depending on the site of muscle injection.
- One of the following applies:
    - The initial treatment is considered sufficient, and the administration of the same dose is recommended.
    - The initial treatment is considered insufficient (defined as an effect which does not last longer than 2 months) and the administration of an increased dose is recommended.
- Both of the following apply:
    - For injection(s) to the flexor muscles, the dose follows the following:
        - Flexor digitorum superficialis: 25-50 Units
        - Flexor pollicis longus: 5-20 Units
        - Flexor digitorum profundus: 20-60 Units
        - Flexor carpi radialis: 20-50 Units
        - Flexor carpi ulnaris: 15-60 Units
    - For injection(s) to the extensor muscles, the dose follows the following:
        - Extensor digitorum communis: 10-25 Units,
        - Extensor pollicis longus: 5-20 Units,
        - Extensor indicis: 5-10 Units,
        - Extensor carpi radialis longus: 5-20 Units,
        - Extensor carpi ulnaris: 5-20 Units

Hemifacial Spasm/Facial Dystonia

Initial

Authorization of 3 months may be granted for the treatment of Hemifacial spasm (HFS)/Facial Dystonia when all of the following criteria are met:

- The requested medication therapy is accepted as first line treatment for primary or secondary Hemifacial spasm (HFS).
- The member has objective documentation of the clinical features consistent with the diagnosis of primary or secondary HFS.
- The member has moderate to severe primary or secondary HFS measured on an objective clinical scale to measure severity, complexity and psychosocial aspects of HFS at baseline with the same scale that will be used during each assessment (the clinical scale is not defined, but the selected scale should provide a comprehensive and sensitive rating tool with both clinical and subjective parameters for HFS to enable a standardized assessment of HFS and treatment outcome).
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The total dose is 25-30 units into the orbicularis oculi, procerus, mentalis, platysma, orbicularis oris and depressor anguli oris on the side of the face affected by the HFS.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Hemifacial spasm (HFS)/Facial Dystonia when all of the following criteria are met:

- The member's Hemifacial spasm (HFS) is measured by an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (the clinical scale is not defined, but the selected scale should provide a comprehensive and sensitive rating tool with both clinical and subjective parameters for HFS to enable a standardized assessment of HFS and treatment outcome).
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The member has documentation of informed clinical decision regarding repeat botulinum injections.
- The member has a reassessment of the degree of persistent moderate to severe HFS.
- The total dose is 25-30 units, with a gradual increase of an additional 5-15 units after 1 year, if necessary, given into the orbicularis oculi, procerus, mentalis, platysma, orbicularis oris and depressor anguli oris on the side of the face affected by the HFS.

Hyperhidrosis

Initial

Authorization of 6 months may be granted for the treatment of Hyperhidrosis when all of the following criteria are met:

- The member has a diagnosis of primary or secondary axillary hyperhidrosis.
- The member has experienced excessive sweating in the axilla lasting 6 months or more.
- The member experiences bilateral symmetric sweating in the axilla.
- The member has a cessation of focal sweating while asleep.
- The member has a failure to respond to other noninvasive conservative management for axillary hyperhidrosis after a 6-month trial (i.e., systemic anticholinergics, tranquilizers, topical dermatologics such as aluminum chloride, tannic acid, or glutaraldehyde, or non-steroid anti-inflammatory medications).
- The member's severe chronic hyperhidrosis is measured on an objective clinical scale at baseline with the same scale that will be used during each assessment (e.g., Hyperhidrosis Disease Severity Scale [HDSS]).
- The member has severe chronic axillary hyperhidrosis manifested by medical complications or skin maceration with secondary infection.
- The member has severe chronic axillary hyperhidrosis associated with an impairment of daily activities.
- The member has significant functional impairment due to hyperhidrosis.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The dose is up to a total of 50 units per axilla and does not exceed 50 units.
- The requested medication will not be used for hyperhidrosis on other body areas of than axillary.
- The member does not have secondary axillary hyperhidrosis due to endocrine, neurologic, medication adverse effects, infection, or malignancy.

- The member has not had surgical debulking of the axillary sweat glands.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Hyperhidrosis when all of the following criteria are met:

- The member's severe chronic hyperhidrosis is measured by an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Hyperhidrosis Disease Severity Scale [HDSS]).
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The member has documentation of informed clinical decision regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent hyperhidrosis and assessment of the previous response to botulinum toxin injection.
- Retreatment is no greater than once every 6 months.
- The dose is between 50-75 units per axilla and does not exceed 75 units.
- The requested medication will not be used for hyperhidrosis on other body areas of than axillary.
- The member does not have secondary axillary hyperhidrosis due to endocrine, neurologic, medication adverse effects, infection, or malignancy.
- The member has not had surgical debulking of the axillary sweat glands.

Laryngeal Dystonia (Spasmodic Dysphonia)

Initial

Authorization of 3 months may be granted for the treatment of Laryngeal Dystonia (Spasmodic Dysphonia) when all of the following criteria are met:

- The member has objective documentation of the clinical features consistent with the diagnosis of adductor type Adductor Spasmodic Dysphonia (ADSD).
- The member has documentation of an objective assessment to rule out non-organic voice disorders.
- The member has moderate to severe chronic ADSD measured on an objective clinical scale at baseline with the same scale that will be used during each assessment (e.g., Voice Handicap Index [VHI] and the Vocal Performance Questionnaire [VPQ]).
- The requested medication is an accepted FDA off-label use first line treatment for members with ADSD.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The initial injection takes place at two separate sites of the thyroarytenoid (TA) and/or lateral cricoarytenoid (LCA) muscle on one side to a total dose between 1.5 to 3.5 units per site.
- A second injection will be given in the contralateral side at a separate time (typically 2 to 4 weeks later) and the dose is titrated to response for members who require bilateral injections for ADSD.
- The member is not receiving bilateral thyroarytenoid (TA) and lateral cricoarytenoid (LCA) injections for ADSD administered concurrently.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Laryngeal Dystonia (Spasmodic Dysphonia) when all of the following criteria are met:

- The member's moderate to severe chronic ADSD is measured by an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Voice Handicap Index [VHI] and the Vocal Performance Questionnaire [VPQ]).
- The member has documentation of informed clinical decision regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent LD and assessment of the previous response to botulinum toxin injection.
- The injections will be given at 12-week intervals.
- The dose is a maximum of 7 units.
- The member is not receiving bilateral thyroarytenoid (TA) and lateral cricoarytenoid (LCA) injections for ADSD administered concurrently.

Neurogenic Bladder

Initial

Authorization of 3 months may be granted for the treatment of Neurogenic Bladder when all of the following criteria are met:

- The member has documentation supporting a diagnosis of neurogenic detrusor overactivity.
- The etiology of the central nervous system impairment which is causing the neurogenic detrusor overactivity is documented.
- The member has moderate to severe neurogenic detrusor overactivity and/or detrusor sphincter dyssynergia assessed by an objective diagnostic test with the same test that will be used during each assessment.
- The member has voiding dysfunction which has failed or become refractory to conservative measures such as lifestyle interventions, bladder training, intermittent catheterizations, pelvic floor muscle exercises and anticholinergic medications or beta-3 adrenergic agonists (in absence of absolute contraindication to the medications) for a minimum of 12 weeks.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- One of the following applies:
    - The member has detrusor overactivity or low bladder compliance and the initial dose of onabotulinumtoxinA (e.g., Botox) is between 100 Units to 200 Units.
    - The member has sphincter dyssynergia or detrusor underactivity with nonrelaxing urethra and the initial dose of onabotulinumtoxinA (e.g., Botox) is between 100 Units to 200 Units.
- The dose of onabotulinumtoxinA (e.g., Botox) 200 Units per treatment must not be exceeded.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Neurogenic Bladder when all of the following criteria are met:

- The member has documentation of informed clinical decisions regarding repeat botulinum injections.
- The member has a reassessment of the degree of persistent neurogenic detrusor overactivity and an assessment of their previous response to botulinum toxin.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- One of the following:
    - The member has detrusor overactivity or low bladder compliance and a subsequent dose of onabotulinumtoxinA (e.g., Botox) is between 100 Units to 200 Units.
    - The member has sphincter dyssynergia or detrusor underactivity with nonrelaxing urethra and a subsequent dose of onabotulinumtoxinA (e.g., Botox) is between 100 Units to 200 Units.
- The dose of onabotulinumtoxinA (e.g., Botox) 200 Units per treatment is not exceeded.

Overactive Bladder (OAB)/Urinary Incontinence (UI)

Initial

Authorization of 3 months may be granted for the treatment of Overactive Bladder (OAB)/Urinary Incontinence (UI) when all of the following criteria are met:

- The member has documentation supporting a diagnosis of refractory overactive bladder (OAB).
- The OAB has been diagnosed by a history and physical exam and a urine analysis to rule out infection or blood in the urine.
- The member has moderate to severe OAB assessed on an objective scale at baseline with the same scale that will be used during each assessment (e.g., Overactive Bladder Symptom Score [OABSS], International Prostate Symptom Score–Storage Subscore [IPSS-S], the modified Urgency Severity Scale [USS], and hypersensitive bladder [HSB]).
- The member has tried conservative treatment (e.g., education of normal bladder function, self-care practices, behavioral modifications, stress management practices, manual physical therapy, and combination therapy).
- The member's symptoms are refractory to a minimum of 12 weeks of standard of care treatment (e.g, anticholinergic or beta-3 adrenergic agonists) or the member has an absolute contraindication to the medications.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The total dose is 100 units per treatment session.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Overactive Bladder (OAB)/Urinary Incontinence (UI) when all of the following criteria are met:

- The member's moderate to severe OAB assessed on an objective scale at baseline with the same scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Overactive Bladder Symptom Score [OABSS], International Prostate Symptom Score–Storage Subscore [IPSS-S], the modified Urgency Severity Scale [USS], and hypersensitive bladder [HSB]).
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The total dose is 100 units per treatment session.

- The member has documentation of informed clinical decision regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent OAB and an assessment of the previous response to botulinum toxin.
- The member has documentation of a positive response to the initial onabotulinumtoxinA (e.g., Botox) injections.

Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS)

Initial

Authorization of 3 months may be granted for the treatment of Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS) when all of the following criteria are met:

- The member has a diagnosis of Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS) established based on symptoms, frequency and cystoscopic findings consistent with the disease.
- The IC/BPS is refractory or the member has failed all other management options for a minimum of 6 months including:
    - Conservative management/standard of care which may consist of education of normal bladder function, self-care practices, behavioral modifications, stress management practices, manual physical therapy, and combination therapy
    - Pharmacological therapy (at least 1 agent)
    - Bladder instillations
    - Hydrodistention
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The total dose is 100 units per treatment session.
- The botulinum toxin injection is being injected via cystoscopy.
- The administration of the requested medication includes injection into the bladder.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS) when all of the following criteria are met:

- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The total dose is 100 units per treatment session.
- The member has documentation of informed clinical decision regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent IC/BPS and an assessment of the previous response to botulinum toxin injection.
- The member has a positive response to initial injections.
- The botulinum toxin injection must be injected via cystoscopy.
- The administration of the requested medication includes injection into the bladder.

Reference number(s)
2170-A

Sialorrhea

Initial

Authorization of 3 months may be granted for the treatment of Sialorrhea with rimabotulinumtoxinB (e.g., Myobloc) when all of the following criteria are met:

- The member has documentation which supports a diagnosis of sialorrhea.
- The etiology of the impairment which is causing the sialorrhea is documented.
- The member has moderate to severe sialorrhea assessed by an objective scale at baseline with the same scale that will be used during each assessment (e.g., Thomas-Stonell drooling severity scale and Thomas-Stonell drooling frequency scale).
- The member has failed conservative measures such as observation, positioning, behavioral therapies, speech therapy and pharmacological therapy.
- One of the following:
    - The requested medication is administered via ultrasound guidance to ensure delivery into the submandibular gland.
    - The requested medication is administered via ultrasound guidance to ensure delivery into the parotids unless the clinician is experienced and is relying on landmarks.
- The requested medication is rimabotulinumtoxinB (e.g., Myobloc).
- The dose of rimabotulinumtoxinB (e.g., Myobloc) is 1,500 Units to 3,500 Units; with 500 Units to 1,500 Units per parotid gland and 250 Units per submandibular gland.

Authorization of 4 months may be granted for the treatment of Sialorrhea with incobotulinumtoxinA (e.g., Xeomin) when all of the following criteria are met:

- The member has documentation which supports a diagnosis of sialorrhea.
- The etiology of the impairment which is causing the sialorrhea is documented.
- The member has moderate to severe sialorrhea assessed by an objective scale at baseline with the same scale that will be used during each assessment (e.g., Thomas-Stonell drooling severity scale and Thomas-Stonell drooling frequency scale).
- The member has failed conservative measures such as observation, positioning, behavioral therapies, speech therapy and pharmacological therapy.
- One of the following:
    - The requested medication is administered via ultrasound guidance to ensure delivery into the submandibular gland.
    - The requested medication is administered via ultrasound guidance to ensure delivery into the parotids unless the clinician is experienced and is relying on landmarks.
- The requested medication incobotulinumtoxinA (e.g., Xeomin).
- The dose of incobotulinumtoxinA (e.g., Xeomin) is a total dose of 100 Units per treatment session consisting of 30 Units per parotid gland and 20 Units per submandibular gland.
- IncobotulinumtoxinA (e.g., Xeomin) will be used for intramuscular or intraglandular injection in the parotid and submandibular glands only.

Authorization of 6 months may be granted for the treatment of Sialorrhea with abobotulinumA (e.g., Dysport) when all of the following criteria are met:

- The member has documentation which supports a diagnosis of sialorrhea.
- The etiology of the impairment which is causing the sialorrhea is documented.

- The member has moderate to severe sialorrhea assessed by an objective scale at baseline with the same scale that will be used during each assessment (e.g., Thomas-Stonell drooling severity scale and Thomas-Stonell drooling frequency scale).
- The member has failed conservative measures such as observation, positioning, behavioral therapies, speech therapy and pharmacological therapy.
- One of the following:
    - The requested medication is administered via ultrasound guidance to ensure delivery into the submandibular gland.
    - The requested medication is administered via ultrasound guidance to ensure delivery into the parotids unless the clinician is experienced and is relying on landmarks.
- The requested medication is abobotulinumA (e.g., Dysport).
- The dose of abobotulinumA (e.g., Dysport) is 15 units per gland (submandibular, parotid or both) either unilaterally or bilaterally.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Sialorrhea when all of the following criteria are met:

- The member has moderate to severe sialorrhea assessed by an objective scale at baseline with the same scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Thomas-Stonell drooling severity scale and Thomas-Stonell drooling frequency scale).
- The member has documentation of informed clinical decision regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent sialorrhea and an assessment of previous response to botulinum toxin injection.
- One of the following applies:
    - The requested medication is rimabotulinumtoxinB (e.g., Myobloc) and the dosage is 1,500 Units to 3,500 Units; 500 Units to 1,500 Units per parotid gland and 250 Units per submandibular gland; no more frequent than every 12 weeks.
    - The requested medication is incobotulinumtoxinA (e.g., Xeomin) and the dosage is 100 Units per treatment session consisting of 30 Units per parotid gland and 20 Units per submandibular gland, no sooner than every 16 weeks.
    - The requested medication is abobotulinumtoxinA (e.g., Dysport) and the dosage is 15 to 75 units injected per gland (submandibular, parotid or both) either unilaterally or bilaterally with intervals of 4 to 6 months between treatments.

Upper and Lower Spasticity

Initial

Authorization of 3 months may be granted for the treatment of Upper and Lower Spasticity when all of the following criteria are met:

- The member has objective documentation of the clinical features consistent with the diagnosis of spasticity.

- The member has moderate to severe chronic spasticity assessed by an objective scale at baseline with the same scale that will be used during each assessment.
- The clinical treatment goals are documented.
- The use of electromyography, electrical stimulation, and/or ultrasonography, rather than site pain or tenderness, is being used to determine injection site(s) for botulinum toxin especially for spastic conditions of the face, neck, and upper extremity.
- The dosage of the requested medication is divided among selected muscles at a given treatment session.
- One of the following applies:
    - The requested medication is onabotulinumtoxinA (e.g., Botox) for an adult member and the dose does not exceed a total dose of 400 Units for the lower limb, or a total of 600 units per treatment session of multiple limbs.
    - The requested medication is onabotulinumtoxinA (e.g., Botox) for a pediatric member and the dose for upper limb spasticity does not exceed a dose of 3-6 Units/kg up to a maximum 200 Units per upper limb. The total dose for lower limb spasticity does not exceed a dose of 4-8 Units/kg up to a maximum 300 Units per lower limb.
    - The requested medication is abobotulinumtoxinA (e.g., Dysport) for an adult and the dose does not exceed a dose of 500-1000 Units for the upper limb, 1000 Units for the lower limb, or a total dose of 1500 Units per treatment session of multiple limbs.
    - The requested medication is abobotulinumtoxinA (e.g., Dysport) for a pediatric member and the total dose for upper limb spasticity does not exceed a dose of 8-15 Units/kg per upper limb up to a maximum 1500 Units per upper limb. The total dose for lower limb spasticity does not exceed a dose of 10-15 Units/kg per lower limb up to a maximum 1000 Units per lower limbs, or a total dose of 1500 Units per treatment session of multiple limbs.
    - The requested medication is incobotulinumtoxinA (e.g., Xeomin) for an adult member and the total dose does not exceed a dose of 400 Units for the upper limb, 400 Units for the lower limb, or a total dose of 600 Units per treatment session of multiple limbs.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Upper and Lower Spasticity when all of the following criteria are met:

- The member has documentation of informed clinical decision regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent spasticity and an assessment of the previous response to botulinum toxin injection.
- The member's moderate to severe chronic spasticity is measured by an objective clinical scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment.
- The use of electromyography, electrical stimulation, and/or ultrasonography, rather than site pain or tenderness, is being used to determine injection site(s) for botulinum toxin especially for spastic conditions of the face, neck, and upper extremity.
- One of the following applies:

- The requested medication is onabotulinumtoxinA (e.g., Botox) and the dose for both upper limb and lower limb spasticity in adults is based on the muscles affected, severity of muscle spasticity, prior response and adverse reaction history following treatment with botulinum toxins. The dose is divided among selected muscles at a given treatment session. The dose in adults does not exceed 400 Units for the upper limb, 400 Units for the lower limb, or a total dose of 600 Units per treatment session of multiple limbs per treatment session when clinically justified and supported by documentation in the medical record.
- The requested medication is onabotulinumtoxinA (e.g., Botox) and the dose for a pediatric beneficiary is based on the muscles affected and severity of muscle spasticity. The dose is divided among selected muscles at a given treatment session. The total dose for upper limb spasticity does not exceed a dose of 3-6 Units/kg up to a maximum 200 Units per upper limb. The total dose of onabotulinumtoxinA (e.g., Botox) for lower limb spasticity does not exceed a dose of 4-8 Units/kg up to a maximum 300 Units per lower limb.
- The requested medication is abobotulinumtoxinA (e.g., Dysport) and the dose for adults is based on the muscles affected, severity of muscle spasticity, prior response and adverse reaction history following treatment with botulinum toxins. The dose is divided among selected muscles at a given treatment session. The dose in adults for upper limb spasticity does not exceed between 500-1000 Units divided among selected muscles at a given treatment session. The maximum total dose (upper and lower limb combined) for the treatment of spasticity in adults is 1500 Units when clinically justified and supported by documentation in the medical record.
- The requested medication is abobotulinumtoxinA (e.g., Dysport) and the dose for pediatric members for upper limb spasticity must not exceed a dose of 8-15 Units/kg per upper limb up to a maximum 1500 Units per upper limb. The total dose for lower limb spasticity must not exceed a dose of 10-15 Units/kg per lower limb up to a maximum 1000 Units per lower limbs. The maximum total dose (upper and lower limb combined) is 1500 Units per treatment session of multiple limbs when clinically justified and supported by documentation in the medical record.
- The requested medication is incobotulinumtoxinA (e.g., Xeomin) and the dose for adults is based on the muscles affected, severity of muscle spasticity, prior response and adverse reaction history following treatment with botulinum toxins. The dose is divided among selected muscles at a given treatment session. The subsequent dose does not exceed a dose of 400 Units for the upper limb, 400 Units for the lower limb, or a total dose of 600 Units per treatment session of multiple limbs when clinically justified and supported by documentation in the medical record.

Strabismus

Initial

Authorization of 3 months may be granted for the treatment of Strabismus when all of the following criteria are met:

- The member has objective documentation of the clinical features consistent with the diagnosis of strabismus.
- The member has moderate to severe strabismus assessed by objective assessment at baseline with the same scale that will be used during each assessment (e.g., Ashworth Scale score and the Tardieu Scale).
- The member has documentation of clinical objective treatment goals.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The dose is 1.25 units to 2.5 units into any one muscle.

Continuation of Therapy

Authorization of 12 months may be granted for the treatment of Strabismus when all of the following criteria are met:

- The member has moderate to severe strabismus assessed by an objective scale at baseline with the same scale after each diagnostic procedure and at each follow-up assessment using the same scale during each assessment (e.g., Ashworth Scale score and the Tardieu Scale).
- The member has documentation of informed clinical decision regarding repeat botulinum toxin injection.
- The member has a reassessment of the degree of persistent strabismus and an assessment of the previous response to botulinum toxin injection.
- The requested medication is onabotulinumtoxinA (e.g., Botox).
- The dose is 1.25 units to 2.5 units into any one muscle.

Dosage and Administration[1]

- Botulinum toxin dosing must be used in accordance with the United States Food and Drug Administration (FDA) approved labeling.
- For off-label botulinum toxin use without an FDA approved dosing indication, the qualified health care professional must provide robust published clinical evidence to support the dosing use.
- For new FDA approved indications for botulinum toxin serotype or dosing recommendations after the effective date of this policy, the qualified health care professional must provide the updated published FDA prescribing information to support the use of the botulinum toxin serotype or dose.

References

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6. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
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