UTILIZATION REVIEW CRITERIA

Botox iCare Criteria #646.00

BOTULINUM TOXINS – CPT CODE: 64612

Coverage Indications, Limitations, and/or Medical Necessity: iCare will consider Botox to be considered a medically necessary service for the following ophthalmological FDA-labeled indications and other indications as specified below:

FDA Indications for Botox®:

- Strabismus and blepharospasm associated with dystonia in patients 12 years of age and older
- Benign essential blepharospasm
- Facial nerve (cranial nerve VII) disorders in patients 12 years of age and older

Off-label Indications for Botox®:

- Synkinetic closure of the eyelid associated with VII cranial nerve aberrant regeneration (i.e., hemi facial spasm in adults)

FDA Indications for Dysport®

- To treat increased muscle stiffness in people 2 years of age and older with spasticity

Off-label Indications for Dysport®

- Blepharospasm in adults
- Hemifacial spasm in adults (cranial nerve VII disorder)

FDA Indications for Xeomin®

- Treatment of Blepharospasm in patients 18 years of age and older iCare will consider Botox to be considered a medically necessary service if: the following non- ophthalmological FDA-labeled indications and other indications as specified below: **FDA Indications for Botox®:**
- Cervical dystonia to reduce the severity of abnormal head position and neck pain (i.e., spasmodic torticollis) in patients 16 years of age and older
- Severe primary axillary hyperhidrosis is inadequately managed with topical agents. Patients should be evaluated for potential causes of secondary hyperhidrosis (i.e., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease in patients 18 years of age and older
- Upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris) and finger flexors (flexor digitorum profundus and flexor digitorum sublimis)
- Prophylaxis of headaches in adult patients with chronic migraine (> 15 days per month with headache lasting
- 4 hours a day or longer) in patients 18 years of age and older

  Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (i.e., spinal cord injury (SCI), multiple sclerosis (MS)) in adults who have an inadequate response to or are intolerant of anticholinergic medication

- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of anticholinergic medication
- Lower limb spasticity in adult patients to decrease the severity of lower limb spasticity (i.e., increased muscle tone) in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus)
- Spastic hemiplegia in patients 2 years of age and older • Spasticity related to stroke in patients 2 years of age and older

Off-label Indications for Botox®:

Botox® is used for a wide range of off-label uses. The use of Botox® may be considered a medically necessary offlabel indication for the treatment of dystonia or lower limb spasticity resulting in functional impairment (interference with joint function, mobility) and/or pain in patients with any of the following hereditary, acquired, degenerative, or demyelinating diseases of the central nervous system:

- Synkinetic closure of the eyelid associated with VII cranial nerve aberrant regeneration (e.g., hemi facial spasm in adults)
- Isolated oromandibular dystonia in adults
- Laryngeal dystonia (spastic dysphonia) for adduction type (ADSD)
- Focal limb dystonia
- The use of Botox® may be considered medically necessary in patients with esophageal achalasia who are considered poor surgical candidates
- The use of Botox® may be considered medically necessary as treatment of chronic anal fissure
    - Bothersome simple motor tics in adolescents and adults when the benefits of treatment outweigh the risks
- Severely disabling or aggressive vocal tics in older adolescents and adults when the benefits of treatment outweigh the risks

FDA Indications for Dysport®

To treat cervical dystonia (CD) in adults 18 years of age and older

- To treat increased muscle stiffness in people 2 years of age and older with spasticity

Off-label Indications for Dysport®

- Isolated oromandibular dystonia in adults

FDA Indications for Xeomin®

- Treatment in long-lasting (chronic) drooling (sialorrhea) in patients 2 years of age and older
- Treatment of abnormal head position and neck pain with cervical dystonia (CD) in patients 18 years of age and older. Treatment of increased muscle stiffness in the arm because of upper limb spasticity in adults
- Treatment of increased muscle stiffness in the arm in children 2 to 17 years of age with upper limb spasticity, excluding spasticity caused by cerebral palsy

FDA Indications for Myobloc®

- Treatment of abnormal head position and neck pain that happens with cervical dystonia (CD) in patients 18 years of age and older
- Treatment of long-lasting (chronic) drooling (sialorrhea) in patients 18 years of age and older

Limitations:

Surgery should not be performed solely to improve vision under the following circumstances:

- The patient does not desire surgery.
- Before consideration of coverage may be made it should be established that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions when applicable.
- It is expected that a patient will not receive continued injections of botulinum toxin if treatment failure occurs after 2 consecutive injections, using maximum dose for the size of the muscle.
- Medical record documentation maintained by the ordering/referring physician should include the following elements in the event of a post payment review:
    - documentation of unsuccessful conventional methods of treatment such as the timing and duration of medication, and/or physical therapy, and/or other appropriate methods used to control and/or treat spastic conditions (statement outlining specific past history is acceptable).
- dosage and frequency of the injections.
- support of the clinical effectiveness of the injections.
- specify the site(s) injected

- Coverage of Botox® for certain lower limb spasticity conditions (i.e., cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis) will be limited to those conditions when there is spasticity of central nervous system origin. All other uses in the treatment of other types of spasm, including smooth muscle types, will be considered as investigational and therefore, noncovered.
- For Myobloc®, a USPDI revision dated December 5, 2005, reversed their decision to allow treatment of spasticity caused by stroke or brain injury listing under “Acceptance not established”. The USPDI revision further states, “The data describing the treatment of Botulinum toxin type B for upper limb spasticity are limited and inconclusive. In a single, randomized, placebo-controlled trail, BTX-B did not demonstrate a benefit in reducing muscle tone in the elbow, wrist or finger flexors in post-stroke patients. However, improvements in upper limb spasticity were reported in a few small open- labeled trials presented in abstract and/or poster forms”. Therefore, effective 11/01/2006, this indication will no longer be allowed.

Documentation Requirements

- All documentation must be maintained in the patient's medical record and made available upon request. *The provider has a responsibility to maintain a record for possible post payment review.*
- Every page of the record must be legible and include appropriate patient identification information (ex. complete name, date of birth, dates of service[s]).
- The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- Office notes supplying documentation of complaints or symptomatology for visual disturbances and the effect on activities of daily living.
- Diagnostic test results.
- Documentation of risk, benefits, and alternatives having been explained to the patient and/or the patient's legal guardian.
- Documentation of a statement that the patient desires to proceed with the procedure must be obtained from the patient and/or the patient's legal guardian.
- Pre-operative notes must be signed by the provider that will be performing the procedure.
- Payment will be allowed for one injection per site regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part, such as, a single limb, eyelid, face, neck, etc.

Definition and Background:

Clostridium botulinum toxin describes a family of neurotoxins produced by the anaerobic bacteria of the species C. botulinum. There are seven distinct serotypes of botulinum toxin: A, B, C, D, E, F and G. All botulinum neurotoxin serotypes are understood to produce their clinical effect by blocking the release of the neurotransmitters, principally acetylcholine, from nerve endings. There are four distinct serotype A botulinum toxin therapeutic products and one serotype B botulinum toxin product that have been approved by the U.S. Food and Drug Administration (FDA):

- OnabotulinumtoxinA (Botox®)
- AbobotulinumtoxinA (Dysport®)
- IncobotulinumtoxinA (Xeomin®)
- PrabotulinumtoxinA-xvfs (Jeuveau ®)-indicated for cosmetic use only
- RimabotulinumtoxinB (Myobloc®)

Whether a botulinum toxin is produced from the same or a different serotype producing strain, they undergo different manufacturing processes which yield differences in the size and weight of the molecules. Because of this, Botox®, Dysport®, Xeomin® and Myobloc®, as well as other type A products available internationally, are not interchangeable. They are chemically, pharmacologically and clinically distinct.

Botulinum toxin injections are used to treat various focal muscle spastic disorders and excessive muscle contractions such as dystonias, spasms, twitches, etc. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical-denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively.

Sources:

Portions of the criteria herein may have been adopted in whole or in part from Local Coverage Determinations as provided by the applicable fiscal intermediary and/or criteria from certain health plan partners.

- Biologics License Application: 103000, 125274, 125360, 103846
- First Coast Service Options, Inc. Local Coverage Determination Reference Article: Billing and Coding: Botulinum Toxins (A57715). Jacksonville, FL: First Coast; effective January 1, 2024.
- First Coast Service Options, Inc. Local Coverage Determination (LCD): Botulinum Toxins (L33274). Jacksonville, FL: First Coast; effective March 21, 2021.
- Food and Drug Administration. Center for Drug Evaluation and Research Application Number: BLA 103000 S-5215 (Botox Injection). Silver Spring, MD: FDA; October 15, 2010. Ipsen Biopharm Ltd. Dysport. Prescribing Information. Wrexham, UK: Ipsen Biopharm. September 2023.
- Merz Pharmaceuticals, LLC. Xeomin. Prescribing Information. Raleigh, NC: Merz Therapeutics U.S. September 2023.
- Solstice Neurosciences, LLC. Myobloc. Prescribing Information. Rockville, MD: Solstice Neurosciences; March 2021.

REVIEW AND REVISION HISTORY		
Date	**Description**	**Approver & Title**
January 12, 2026	Approval by PAC	Approval by PAC
February 21.2025	Revised criteria, Approved by PAC approved Via email.	Approved by PAC
January 13, 2025	Approval by PAC	Approval by PAC
June 15, 2024	Administrative revisions (non-clinical)	Dr Smith Blanc, Director of UM
June 1, 2024	Administrative revisions (non-clinical)	Dr. Smith Blanc, Director of UM
January 15, 2024	Approval by PAC	Approved by PAC
November 2023	Administrative revisions (non-clinical)	Dr. Smith Blanc, Director of UM
July 17, 2023	Approval by PAC (clinical documentation changes made)	Approved by PAC
January 23, 2023	Approval by PAC	Approved by PAC
January 17, 2022	Approval by PAC	Approved by PAC
January 18, 2021	Approval by PAC	Approved by PAC
January 27, 2020	Approval by PAC	Approved by PAC
October 12, 2020	Approval by PAC	Approved by PAC
April 13, 2020	Approval by PAC	Approved by PAC
January 28, 2019	Approval by PAC	Approved by PAC
January 29, 2018	Approval by PAC	Approved by PAC
January 9, 2017	Approval by PAC	Approved by PAC