Botulinum Toxins Injections
Medical Necessity Checklist

L33274

A57715 Billing and Coding Article

Patient Name:

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 three 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®), RimabotulinumtoxinB (Myobloc®)

Effective 7/1/20: Botulinum Toxin procedures require prior authorization - see the link for applicable CPT codes and regulation: CMS Prior Authorization | CMS Prior Authorization Flowchart

CODING

Drug Administration Codes	HCPCS (Drug Code)	
64612 - Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)	J0585 - Injection, OnabotulinumtoxinA, 1 Unit	J0587 - Injection, RimbotulinumtoxinB, 100 Units
64615 - Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)	J0586 - Injection, AbobotulinumtoxinA, 5 Units	J0588 - Injection, IncobotulinumtoxinA, 1 Unit

Refer to Local Coverage Determination L33274 for the list of covered ICD-10 diagnosis codes.

COVERAGE INDICATIONS

Botulinum toxins will be considered medically reasonable and necessary when administered for treatment of the following FDA-labeled indications and other indications as specified below:

OnabotulinumtoxinA (Botox®)

□ strabismus and blepharospasm associated with dystonia
□ benign essential blepharospasm
□ facial nerve (cranial nerve VII) disorders in patients 12 years of age and older
□ cervical dystonia to reduce the severity of abnormal head position and neck pain (i.e., spasmodic torticollis)
□ severe primary axillary hyperhidrosis inadequately managed with topical agents. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. □ prophylaxis of headaches in adult patients with chronic migraine (> 15 days per month with headache lasting 4 hours a day or longer).
□ 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).
□ treatment of urinary incontinence due to detrusor over activity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of anticholinergic
□ 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 an 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
*spasticity related to

AbobotulinumtoxinA (Dysport®)

□ the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients;
□ the treatment of spasticity in adults;
□ the treatment of lower limb spasticity in pediatric patients 2 years of age and older.

IncobotulinumtoxinA (Xeomin®)

□ chronic sialorrhea in adult patients
□ adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients
□ blepharospasm in adults previously treated with onabotulinumtoxina (Botox)
□ upper limb spasticity in adult patients

RimabotulinumtoxinB (Myobloc®)

□ cervical dystonia to reduce the severity of abnormal head position and neck pain (i.e., spasmodic torticollis)

OFF-LABEL COVERAGE INDICATIONS

□ dynamic muscle contracture in pediatric or adult cerebral palsy patients
□ synkinetic closure of the eyelid associated with VII cranial nerve aberrant regeneration (e.g., hemi facial spasm)
□ idiopathic torsion dystonia
□ symptomatic torsion dystonia□ oromandibular dystonia
□ spasmodic dysphonia
□ orofacial dyskinesia
□ focal hand dystonia (e.g., writer's cramp)
□ hereditary spastic paraplegia
□ neuromyelitis optica
□ Schilder's disease

Other instances where Botox® may be considered medically necessary

□ patients with laryngeal spasm and torticollis (whether congenital, due to child birth injury, or traumatic).
□ patients with achalasia who have not responded to dilation therapy or who are considered poor surgical candidates.
□ as treatment of chronic anal fissure.
□ treatment of gustatory hyperhidrosis (secondary) with Botox® may be considered medically necessary in patients with medical complications; such as skin maceration with secondary infections, or significant functional impairments.

□ benign essential blepharospasm
□ hemifacial spasm in adults
□ severe primary axillary hyperhidrosis inadequately managed with topical agents. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease.

□ None

□ sialorrhea
The treatment of sialorrhea due to conditions such as motor neuron disease or Parkinson's disease in those patients who have failed to respond to a reasonable trial of traditional therapies (e.g., anticholinergics and speech therapy) or who have a contraindication to or cannot tolerate anticholinergic therapy, will be allowed for coverage.

LIMITATIONS

□ Coverage of Botox® for certain lower limb spasticity conditions (e.g., 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.

□ 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.

□ 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.

□ 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.

DOCUMENTATION REQUIREMENTS

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).
□ Support of the clinical effectiveness of the injections.
□ Dosage and frequency of the injections.

□ Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, 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.
□ Specify the site(s) injected.
□ Documentation must be available upon request.
□ 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.

Checklist completed by : | **Date:**