

L33274		Patient Name:	
A57715 Billing and Coding Article			
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, RimabotulinumtoxinB, 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®)		AbobotulinumtoxinA (Dysport®)	
<input type="checkbox"/> strabismus and blepharospasm associated with dystonia <input type="checkbox"/> benign essential blepharospasm <input type="checkbox"/> facial nerve (cranial nerve VII) disorders in patients 12 years of age and older <input type="checkbox"/> cervical dystonia to reduce the severity of abnormal head position and neck pain (i.e., spasmodic torticollis) <input type="checkbox"/> 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. <input type="checkbox"/> prophylaxis of headaches in adult patients with chronic migraine (> 15 days per month with headache lasting 4 hours a day or longer).		<input type="checkbox"/> 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. <input type="checkbox"/> 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 stroke	
<input type="checkbox"/> 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). <input type="checkbox"/> 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 medication.		<input type="checkbox"/> chronic sialorrhea in adult patients <input type="checkbox"/> adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients; <input type="checkbox"/> blepharospasm in adults previously treated with onabotulinumtoxinA (Botox) <input type="checkbox"/> upper limb spasticity in adult patients	
<input type="checkbox"/> idiopathic torsion dystonia <input type="checkbox"/> symptomatic torsion dystonia <input type="checkbox"/> orofacial dyskinesia		<input type="checkbox"/> cervical dystonia to reduce the severity of abnormal head position and neck pain (i.e., spasmodic torticollis)	
<input type="checkbox"/> focal hand dystonia (e.g., writer's cramp) <input type="checkbox"/> hereditary spastic paraplegia <input type="checkbox"/> neuromyelitis optica <input type="checkbox"/> Schilder's disease			
OFF-LABEL COVERAGE INDICATIONS			
<input type="checkbox"/> dynamic muscle contracture in pediatric or adult cerebral palsy patients <input type="checkbox"/> synkinetic closure of the eyelid associated with VII cranial nerve <input type="checkbox"/> aberrant regeneration (e.g., hemi facial spasm)		<input type="checkbox"/> benign essential blepharospasm <input type="checkbox"/> hemifacial spasm in adults <input type="checkbox"/> 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.	
<input type="checkbox"/> 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.			
Other instances where Botox® may be considered medically necessary <input type="checkbox"/> patients with laryngeal spasm and torticollis (whether congenital, due to child birth injury, or traumatic). <input type="checkbox"/> patients with achalasia who have not responded to dilation therapy or who are considered poor surgical candidates. <input type="checkbox"/> as treatment of chronic anal fissure. <input type="checkbox"/> 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.			
LIMITATIONS			
<input type="checkbox"/> 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.			
<input type="checkbox"/> 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.			
<input type="checkbox"/> 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.			
<input type="checkbox"/> 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:			
<input type="checkbox"/> 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). <input type="checkbox"/> Support of the clinical effectiveness of the injections. <input type="checkbox"/> Dosage and frequency of the injections. <input type="checkbox"/> Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). <input type="checkbox"/> The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient. <input type="checkbox"/> Specify the site(s) injected. <input type="checkbox"/> Documentation must be available upon request. <input type="checkbox"/> 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:
<i>Disclaimer: The content of the checklists were created as an educational tool. Use of these documents are not intended as a replacement for the documentation requirements published in National or Local Coverage Determinations, or the CMS's documentation guidelines, written law or regulations. Medicare policy changes frequently; therefore, Providers/Departments are reminded to review current National and Local Coverage Determination and Policy Articles for specific documentation and coding guidelines.</i>			