



MEDICAL POLICY

Date Reviewed: 02/25/00, 02/19/01, 09/28/01, 03/22/02, 08/27/04, 09/23/05, 04/20/07, 12/28/09, 02/05/10, 04/15/11

Subject: Botox, Dysport, Myobloc, and Xeomin (botulinum toxin, onabotulinumtoxinA, abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB) injections

Description: Botox is a neuromuscular blocker (neurotoxin) produced by fermentation of the bacterium *Clostridium botulinum*. Botox interferes with neuromuscular transmission, temporarily paralyzing the affected muscle through depolarization. Botulinum toxins are not interchangeable. Each preparation has distinct pharmacological and clinical profiles specified on the product label. Unit potency and biological activity have been determined for each toxin, and the units must be calculated individually based on the specific toxin.

Indications of Coverage:

The use of Botox (onabotulinumtoxinA only) is considered medically necessary for the treatment of migraine headaches in individuals over the age of 18 when all of the following criteria are met:

A history and physical performed by a neurologist documents headaches of at least four hours duration per day for at least fifteen days per month during each of the previous three months and medication use or abuse as the cause of the headaches has been ruled out

The medical record documents the use of analgesic medications for at least fifteen days of each of the previous three months AND the regular and consistent use of at least three different headache prophylactic medication classes (for example, beta blocking agents (propranolol, atenolol, metoprolol), calcium channel blocking agents (diltiazem, verapamil), tricyclics (amitriptyline, imipramine, nortriptyline), and anticonvulsants (phenobarbital, gabapentin)) for three consecutive months of the past six months

If criteria for approval are met, one injection may be approved. A second injection may be approved at twelve weeks when the medical record documents at least six fewer days with headaches during the previous month when compared with the baseline measurement. A third injection may be approved at 24 weeks when the medical record documents at least eight fewer days with headaches during the previous month when compared with the baseline measurement. Subsequent injections may be allowed at one every twelve weeks when the medical record continues to document at least eight fewer days with headaches during the previous month when compared with the baseline measurement.

The use of Botox or Dysport (onabotulinumtoxinA, abobotulinumtoxinA) is considered medically necessary for any of the following conditions:

Cervical dystonia (spasmodic torticollis) in adults. (Used to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.) Documentation of sustained abnormal positioning, including degrees of rotation or deviation is required.

Strabismus associated with dystonia

Blepharospasm (involuntary forcible closure of the eyelid due to spasms) associated with dystonia.

Hereditary spastic paraplegia, spastic hemiplegia, or infantile cerebral palsy when spasms or spastic posturing interfere with activities of daily living, or in conjunction with adductor lengthening surgery.

Limb spasticity due to multiple sclerosis or other demyelinating disease of the central nervous system when spasms or spastic posturing significantly interfere with activities of daily living

Spastic dysphonia

Hemifacial spasm (synkinesis) with functional deficits such as drooling, slurred speech and/or severe pain in the involved muscles affecting activities of daily living.

Voiding dysfunction associated with neurologic illness or injury (such as spinal cord injury, multiple sclerosis, cerebrovascular accident) when conventional treatment (at least a three month consistent trial) has failed.

Treatment of painful anal fissure when conventional treatment, including glyceryltrinitrate, stool softeners, diet modification, has failed.

If criteria are met, one treatment may be approved to determine efficacy. If sufficient efficacy is documented, subsequent treatments may be approved in one year increments with review of continued therapeutic response. Injections may be allowed at 12 week intervals. One unit of the applicable code(s) (64612-64614 or 64640) is allowed for each date of service. EMG guidance, 95873 or 95874, may also be allowed. Codes 95860-95872 would not ordinarily be performed on the date of injection.

Myobloc (rimabotulinumtoxinB) is considered medically necessary for:

Cervical dystonia (torticollis) in adults. (Used to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.) Documentation of sustained abnormal positioning, including degrees of rotation or deviation, is required.

If criteria are met, one treatment may be approved to determine efficacy. If sufficient efficacy is documented, subsequent treatments may be approved in one year increments with review of continued therapeutic response. Injections may be allowed at 12 week intervals. One unit of the applicable code(s) (64612-64614 or 64640) is allowed for each date of service. EMG guidance, 95873 or 95874, may also be allowed. Codes 95860-95872 would not ordinarily be performed on the date of injection.

Xeomin (incobotulinumtoxinA) is considered medically necessary for any of the following conditions:

Cervical dystonia (spasmodic torticollis) in adults. (Used to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.) Documentation of sustained abnormal positioning, including degrees of rotation or deviation is required.

Blepharospasm (involuntary forcible closure of the eyelid due to spasms) associated with dystonia in individuals over the age of 18 where there is documentation of the failure of Botox (onabotulinumtoxinA) for the treatment of blepharospasm.

If criteria are met, one treatment may be approved to determine efficacy. If sufficient efficacy is documented, subsequent treatments may be approved in one year increments with review of continued therapeutic response. Injections may be allowed at 12 week intervals. One unit of the applicable code(s) is allowed for each date of service. EMG guidance may also be allowed. EMG testing would not ordinarily be performed on the date of injection.

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

The use of Botox for the treatment of hyperhidrosis (excessive sweating) or sialorrhea (excessive secretion of saliva) is an exclusion of the policy because these conditions are not an illness or injury.

The use of Botox for pain syndromes (including, but not limited to, spinal pain) is considered investigational. There is insufficient peer-reviewed scientific literature supporting the safety and efficacy of the use of botulinum toxin for this indication.

Documentation Required:

Office notes

Physical, occupational, or speech therapy notes

Rationale: Botox has been approved by the US Food and Drug Administration (FDA) for the treatment of cervical dystonia, strabismus, and blepharospasm. It has been widely used for a variety of other conditions, despite limited scientific evidence of its effectiveness for many of these conditions. Studies have shown that Botox is effective for some specific conditions characterized by involuntary spasm of certain muscle groups, such as spastic dysphonia. Botox has been shown to improve gait patterns in patients with cerebral palsy, especially early in a child's development of walking skills, and may limit the need for later surgery.

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Approved by the Medical Director