

Botox® (Botulinum Toxin)



Pharmacy Coverage Policy

Effective Date: September 29, 2006

Revision Date: January 20, 2021

Review Date: January 20, 2021

Line of Business: Medicare, Commercial, HUM Medicaid

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at <http://www.cms.hhs.gov/>. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

Description

Botulinum toxin (BTX) is a neurotoxin produced by clostridium botulinum, a spore forming anaerobic bacillus.

Botulinum toxins inhibit the release of acetylcholine from cholinergic junctions, causing functional denervation of the muscle that result in a localized reduction of muscle activity.

FDA-approved-botulinum toxin products include: Botox (onabotulinumtoxinA), Dysport (abobotulinumtoxinA), Xeomin (incobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), and Jeuveau (prabotulinumtoxinA-xvfs).

Botulinum toxin is supplied as follows:

Botox (onabotulinumtoxinA)

- 50U (cosmetic), 100U, and 200U vacuum-dried powder for solution for injection.

Coverage

Please note the following regarding medically accepted indications:

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Determination

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Botulinum toxin will require prior authorization.

Botox (onabotulinumtoxinA) may be considered medically necessary for ANY of the following indications:

- Achalasia in members with ANY of the following:
 - Advanced age
 - Epiphrenic diverticulum or hiatal hernia
 - Failure of conventional therapy
 - Failure of previous myotomy or pneumatic dilation
 - High risk for complications of myotomy or pneumatic dilation
 - Limited life expectancy
 - Previous esophageal perforation

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- Sigmoid-shaped esophagus
- Blepharospasm
- Cervical dystonia (spasmodic torticollis)
- Chronic anal fissures unresponsive to conservative therapeutic measures (e.g., nitroglycerin ointment).
- Chronic migraine
 - The member has migraines for greater than or equal to 15 days/month, each lasting for more than four hours a day or longer **AND**
 - The member has had previous treatment, intolerance or contraindication to 2 or more preventive therapies after titration to maximum tolerated doses. Preventive therapies include but are not limited to beta-blockers (e.g., propranolol), calcium channel blockers (e.g., diltiazem), anticonvulsants (e.g., topiramate, divalproex sodium), and antidepressants (e.g., venlafaxine)*.
- Excessive salivation (ptyalism/sialorrhea).
- Facial nerve (VII cranial nerve) dystonia, hemifacial or facial spasm.
- Frey's syndrome (gustatory sweating).
- Hereditary spastic paraplegia.
- Infantile cerebral palsy.

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- Infantile esotropia or concomitant strabismus, as an alternative to surgery, or previous failed surgery, when interference with normal visual system development is likely to occur and when spontaneous recovery is unlikely.
- Limb spasticity in children with cerebral palsy in the absence of significantly fixed deformity.
- Upper and/or Lower Limb Spasticity in members 2 years of age and older
- Spasticity in members with multiple sclerosis, stroke, and traumatic brain injury.
- Muscle stiffness in the flexor muscles of the elbows, wrists and fingers.
- Organic writer's cramp (focal hand dystonia).
- Orofacial dyskinesia or jaw-closure dystonia.
- Severe primary axillary hyperhidrosis or palmar hyperhidrosis that significantly interferes with member's daily activities, refractory to greater than six months treatment with topical agents.
- Spasmodic dysphonia (adductor or abductor) or laryngeal dystonia.
- Strabismus, including horizontal strabismus up to 50 prism diopters, vertical strabismus, and persistent VI nerve palsy of one month duration or longer and for blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders.

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- Symptomatic torsion dystonia.
- Urinary incontinence due to detrusor overactivity associated with a neurologic condition OR overactive bladder with symptoms of urge urinary incontinence, urgency and frequency:
 - The member has had previous treatment, contraindication, or intolerance with two formulary muscarinic receptor antagonists (e.g., oxybutynin, trospium)*.

**previous treatment requirement does not apply to Medicare medical requests*

Botulinum toxin will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Botulinum toxin, therapy is not considered medically necessary for members with the following concomitant conditions:

Members would **NOT** be eligible for botulinum toxins, for any other indications, including, but may not be limited to the following:

- Duane's syndrome with lateral rectus muscle weakness
- Gastroparesis
- Headache, episodic migraine, cluster, hemicrania continua
- Neck pain, not related to the indications above
- Chronic musculoskeletal pain
- Secondary strabismus caused by prior surgical over-recession of the antagonist muscle.
- The following limitations apply to Botox (onabotulinumtoxinA) when used in the treatment of urinary incontinence:
 - Acute urinary tract infections and/or acute urinary retention

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- Use of botox (onabotulinumtoxinA) in combination with other anticholinergic agents

All other indications are considered experimental/investigational, as they are not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Members would **NOT** be eligible under the plan for botulinum toxins, for **cosmetic purposes**, including, but not limited to, the following:

- Aging neck
 - Blepharoplasty
 - Canthal rhytide
 - Crow's feet
 - Cutaneous scar (facial wounds)
 - Deep forehead lines
 - Deep nasolabial folds
 - Frown lines
 - Glabellar lines
 - Hyperkinetic facial lines
 - Wrinkles.
- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Botulinum Toxins (Botox).

The potency units of Botox for injection are specific to the preparation and assay method utilized. They are not interchangeable with other botulinum toxin products.

Botulinum toxin (BTX) is the treatment of choice for a variety of spasticity disorders and dystonias. While BTX treatment does not restore normal muscle function, it can help control abnormal muscle functioning.

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The FDA-approved label for Botox (onabotulinumtoxinA) states that it is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders, in patients greater than 12 years old, severe primary axillary hyperhidrosis that is inadequately managed with topical agents, adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia, upper limb spasticity in adult patients and those aged 2 to 17 years of age 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), chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer), and urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have an inadequate response to or are intolerant to anticholinergic medication.

Anal fissures usually heal with conservative therapy; however, those lasting for longer than two months are considered chronic and are unlikely to heal with conservative management. The American Gastroenterological Association lists BTX as one of three treatment options beyond conservative treatment for anal fissure.

Current standard treatment for achalasia involves surgical myotomy or pneumatic dilation. There are certain situations, such as previous esophageal perforation, epiphrenic diverticulum, sigmoid-shaped esophagus, advanced age or concomitant medical problems, failure of previous myotomy or pneumatic dilation, limited life expectancy or patient choice, in which BTX may be favored over other methods.

Daily preventive therapy is warranted when frequent migraines interfere with activity despite acute treatment. Evidenced based guidelines for treatment of migraines provides guidance to the management decisions on the use of preventive therapies which include frequent headache, contraindication to or failure or overuse of acute therapies, adverse events with acute therapies, frequent headaches, recurring migraines that in the patients opinion significantly interferes with daily routines, despite acute treatment. Triptans differ in effectiveness (how fast and how long they work); therefore, more than

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one triptan is recommended for treatment of acute migraines before a trial of Botox for chronic migraines.

The International Continence Society (ICS) has defined overactive bladder (OAB) as a syndrome that consists of the following symptoms: urinary urgency, with or without urgency urinary incontinence, usually with frequency and nocturia, in the absence of causative infection or pathologic conditions and suggestive of underlying detrusor overactivity. OAB appears to be multifactorial in both etiology and pathophysiology. Overactivity of the detrusor muscle – neurogenic or idiopathic in origin – may result in urinary urgency and urgency incontinence. A combined treatment approach using behavioral and pharmaceutical interventions is usually effective in most patients with OAB. Intradetrusor injection of onabotulinumtoxinA, sacral neuromodulation, or peripheral tibial nerve stimulation (PTNS) may be considered for carefully selected patients with severe refractory OAB symptoms or those who are not candidates for pharmaceutical interventions. When using botulinum toxin in the treatment of urinary incontinence, prophylactic antibiotics must be administered 1-3 days prior to treatment, on the treatment day, and 1-3 days post-treatment to reduce the likelihood of procedure related UTI. Due to the potential for drug interactions with botulinum toxin, aminoglycosides should be avoided when selecting a prophylactic antibiotic.

In April 2009 the FDA announced that safety label changes including a boxed warning and a Risk Evaluation and Mitigations Strategy (REMS) would be required for all botulinum toxin products. This is due to three main reasons: 1) Potential for serious risks due to the spread of the toxin beyond the injection site that may lead to systemic botulism. This spreading effect has been reported in both children and adults. 2) The lack of interchangeability among the four licensed botulinum toxin products. 3) Package labeling for each of the botulinum toxin products states that "...units of biological activity [of one botulinum toxin product] cannot be compared to nor converted into units of any other botulinum toxin or any toxin assessed with any other specific assay method."

Provider Claims Codes

All provider claims codes surrounding this topic may not be included in the following table:

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CPT® Codes	Description	Comments
31513	Laryngoscopy, indirect; with vocal cord injection	
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic	
31571	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope	
43201	Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance	
46505	Chemodenervation of internal anal sphincter	
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder	
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral	
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (eg, for blepharospasm, hemifacial spasm)	
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)	
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)	Code effective 01/01/2014
64642	Chemodenervation of one extremity; 1-4 muscle(s)	Code effective 01/01/2014
+64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)	Code effective 01/01/2014
64644	Chemodenervation of one extremity; 5 or more muscles	Code effective 01/01/2014
+64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)	Code effective 01/01/2014
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)	Code effective 01/01/2014
64653	Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day	
67345	Chemodenervation of extraocular muscle	
	Electrical stimulation for guidance in conjunction with	

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+95873	chemodenervation (List separately in addition to code for primary procedure)	
+95874	Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)	
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed	
64650	Chemodenervation of eccrine glands; both axillae	
64647	Chemodenervation of trunk muscle(s); 6 or more muscles	
64650	Chemodenervation of eccrine glands; both axillae	
64647	Chemodenervation of trunk muscle(s); 6 or more muscles	
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed	
HCPC® Codes	Description	Comments
J0585	Injection, onabotulinumtoxinA, 1 unit	
S2340	Chemodenervation of abductor muscle(s) of vocal cord	
S2341	Chemodenervation of adductor muscle(s) of vocal cord	
S2340	Chemodenervation of abductor muscle(s) of vocal cord	
S2341	Chemodenervation of adductor muscle(s) of vocal cord	
ICD® Codes	Description	Comments
0DJ08ZZ	Inspection of Upper Intestinal Tract, Via Natural or Artificial Opening Endoscopic	Code valid for Dates of Service on or after 10/01/2015
3E0F3GC	Introduction of Other Therapeutic Substance into Respiratory Tract, Percutaneous Approach	Code valid for Dates of Service on or after 10/01/2015
3E013GC	Introduction of Other Therapeutic Substance into Subcutaneous Tissue, Percutaneous Approach	Code valid for Dates of Service on or after 10/01/2015
3E023GC	Introduction of Other Therapeutic Substance into Muscle, Percutaneous Approach	Code valid for Dates of Service on or after 10/01/2015

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3E0134Z	Introduction of Serum, Toxoid and Vaccine into Subcutaneous Tissue, Percutaneous Approach	Code valid for Dates of Service on or after 10/01/2015
3E0234Z	Introduction of Serum, Toxoid and Vaccine into Muscle, Percutaneous Approach	Code valid for Dates of Service on or after 10/01/2015

Medical Terms

Abductor - Any muscle that moves one part of the body away from another or away from the middle of the body.

Achalasia - Failure of the lower esophageal sphincter to relax resulting in the inability to pass food from the esophagus into the stomach.

Adductor - Any muscle that moves one part of the body towards another or towards the middle of the body.

Anal Fissure - Tear in the anus.

Axillary - Armpit area.

Blepharospasm - Involuntary closure of the eyes and lids.

Concomitant - Occurring together.

Diaphragm - The thin muscle below the lungs and heart that separates the chest from the abdomen.

Diverticulum - Small pouch in the colon.

Dyskinesia - Involuntary movement.

Dystonia - Movement disorder consisting of a tightening and twisting of a limb.

Equine - Resembling a horse.

Esotropia - One or both eyes turning inward.

Hiatal Hernia - The protrusion of the upper part of the stomach into the thorax through a tear or weakness in the diaphragm.

Hyperhidrosis - Excessive sweating.

Intramuscular - Into a muscle.

Laryngeal - Referring to the voice box.

Myotomy - Surgical incision or division of a muscle.

Orofacial - Relating to the mouth and face.

Palmar - Relating to the palm of the hand.

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Paraplegia - Paralysis of both legs.

Perforation - A hole in the wall of an organ.

Pneumatic Dilation - A treatment that stretches the lower esophageal sphincter (LES) in which an un-inflated balloon is inserted in the throat. Once the tube reaches the point of the LES muscle, the balloon is inflated.

Spasmodic Dysphonia - Irregular voice breaks.

Spasmodic Torticollis - A form of dystonia involving the muscles of the neck. Also called cervical dystonia.

Spastic - Stiff muscles.

Strabismus - Misalignment of the eye.

Subcutaneous - Under the skin.

Thorax - Part of the human torso between the neck and the diaphragm.

Torsion - Twisting of an organ.

Torticollis - Twisting of the neck that causes the head to rotate and tilt on an angle.

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