



Corporate Medical Policy

Botulinum Toxin Injection

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Last Review: 9/2009

Description of Procedure or Service

Botulinum is a family of toxins produced by the anaerobic organism *Clostridia botulinum*. There are 7 distinct serotypes designated as type A, B, C-1, D, E, F, and G. In this country, 2 preparations of botulinum are available, produced by 2 different strains of bacteria: type A (Botox, Dysport) and type B (Myobloc). When administered intramuscularly, all botulinum toxins reduce muscle tone by interfering with the release of acetylcholine from nerve endings.

The label for Botox (OnabotulinumtoxinA) approved by the U.S. Food and Drug Administration (FDA) 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 older than 12 years. The FDA-approved label for Myobloc (RimabotulinumtoxinB) states that it is indicated for the treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain. On April 29, 2009 the FDA approved the use of Dysport (AbobotulinumtoxinA) to treat patients with cervical dystonia.

Dystonia is a general term describing a state of abnormal or disordered tonicity of muscle. As an example, esophageal achalasia is a dystonia of the lower esophageal sphincter, while cervical dystonia is also known as torticollis. Spasticity is a subset of dystonia, describing a velocity-dependent increase in tonic-stretch reflexes with exaggerated tendon jerks. Spasticity typically is associated with injuries to the central nervous system. Spasticity is a common feature of cerebral palsy. Since its FDA approval in 1991, Botox has been used for a wide variety of off-label indications, ranging from achalasia, spasticity after strokes, cerebral palsy, and anal fissures. In addition to widening indications, Botox has also been used in children under 12, particularly for the treatment of cerebral palsy. It is anticipated that Myobloc will be used for the same range of off-label indications as Botox.

After successful extended use of botulinum toxin (usually A), some initial responders become nonresponders. Such secondary nonresponse may occur for a variety of reasons; one cause in a small percentage of patients is the development of antibodies that neutralize the activity of the administered botulinum toxin. These patients are likely to respond to another botulinum toxin type. A clinically useful assay for toxin-reactive antibodies would detect only neutralizing antibodies, as non-neutralizing antibodies can be present in the serum of patients who have not developed resistance to treatment. Assay formats best suited to the clinical laboratory, such as immunoprecipitation, western blot, or enzyme-linked immunosorbent assay, typically do not discriminate between neutralizing and non-neutralizing antibodies and would thus generate false-positive results in some patients.

***Please note that the US Food & Drug Administration (FDA) now requires a boxed warning and a Risk Evaluation and Mitigation Strategy (REMS) for all Botulinum Toxin products. Refer to the FDA Website for additional information located at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm174949.htm>.

Policy: Botulinum Toxin Injection

Policy

BCBSNC will provide coverage for Botulinum Toxin Injection when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When Botulinum Toxin Injection is covered

1. Botulinum toxin may be considered medically necessary to treat the following FDA labeled indications:
 - a. [Strabismus](#),
 - b. [Blepharospasm](#),
 - c. Facial nerve (VII) disorders, such as [hemifacial spasm](#), or
 - d. [Cervical dystonia](#) (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury). (see "Policy Guidelines" section for use of Botulinum Toxin for this indication).
2. Botulinum toxin may be considered medically necessary the off-labeled FDA indications for the treatment of [dystonia](#)/spasticity resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake) and/or pain in patients with the following hereditary, degenerative, or demyelinating diseases of the central nervous system: *****Use of botulinum toxin for off-label indications should only be done when the treating physician has determined that the benefits of the treatment clearly outweigh the risks of the therapy.**
 - a. Idiopathic (primary or genetic) torsion [dystonia](#),
 - b. Symptomatic (acquired) torsion [dystonia](#),
 - c. Oromandibular dystonia (orofacial [dyskinesia](#), Meige syndrome),
 - d. Laryngeal [dystonia](#) and adductor [spasmodic dysphonia](#),
 - e. Organic writer's cramp (focal upper limb [dystonia](#)),
 - f. Hereditary spastic paraparesis,
 - g. Neuromyelitis optica,
 - h. Multiple sclerosis or Schilder's disease,
 - i. Spastic hemiplegia,
 - j. [Spasticity](#) related to stroke,
 - k. Spinal cord or traumatic brain injury,
 - l. Infantile cerebral palsy.

Policy: Botulinum Toxin Injection

3. Botulinum toxin may be considered medically necessary in patients with the following off-labeled FDA indications: *****Use of botulinum toxin for off-label indications should only be done when the treating physician has determined that the benefits of the treatment clearly outweigh the risks of the therapy.**
 - a. Lower esophageal **achalasia** where the patient has not responded to dilation therapy or where the patient is considered a poor surgical candidate,
 - b. Chronic anal fissure,
 - c. Sialorrhea (drooling) associated with Parkinson disease,
 - d. Incontinence due to **detrusor** overreactivity (urge incontinence), either idiopathic or due to neurogenic causes (i.e., spinal cord injury, multiple sclerosis), that is inadequately controlled with anticholinergic therapy.
4. Botulinum toxin may be considered medically necessary in patients with gustatory hyperhidrosis (**Frey's Syndrome**) following parotid surgery.

NOTE: Refer to separate policy number MED1215, titled "Hyperhidrosis, Treatment of " regarding Botulinum toxin injection guidelines for patients with primary Hyperhidrosis.

When Botulinum Toxin Injection is not covered

1. For conditions other than those listed above.
2. Botulinum toxin is considered not medically necessary as a treatment of:
 - a. Wrinkles,
 - b. Other cosmetic indications.
3. Botulinum toxin is considered investigational for other indications, including but not limited to:
 - a. Headaches including migraine, chronic tension, chronic daily, and cervicogenic or "cervicodystonic" headaches,
 - b. Chronic low back pain,
 - c. Joint pain,
 - d. Mechanical neck disorders,
 - e. Neuropathic pain after neck dissection,
 - f. **Myofascial pain syndrome**,
 - g. Pain after hemorrhoidectomy or lumpectomy,
 - h. Tremors such as benign essential tremor (upper extremity),
 - i. Tinnitus,
 - j. Chronic motor **tic** disorder,
 - k. **tics** associated with Tourette syndrome (motor tics),
 - l. Sialorrhea (drooling) except that associated with Parkinson disease,
 - m. Lateral epicondylitis,
 - n. Benign prostatic hyperplasia,
 - o. Interstitial cystitis,

Policy: Botulinum Toxin Injection

- p. [Detrusor](#) overreactivity not due to spinal cord injury,
 - q. [Detrusor sphincteric dyssynergia](#) (after spinal cord injury),
 - r. Piriformis syndrome.
4. The use of assays to detect antibodies to botulinum toxin is considered investigational.

Policy Guidelines

This drug may require prior review. In cases for which botox has been approved in the past, medical records are required yearly to document ongoing effectiveness of botox.

- A. For use of Botulinum toxin for [cervical dystonia \(spasmodic torticollis\)](#) whether congenital, due to child birth injury, or traumatic injury; **ALL** of the following criteria must be met:
- 1. Postural disturbance and pain must be of moderate or greater severity as documented by interference with specific activities of daily living and unresponsive to a trial of appropriate standard conservative therapy that may include non-narcotic analgesics, muscle relaxants and physical modalities; **AND**
 - 2. There are [clonic](#) and/or [tonic](#) involuntary contractions of one or more neck muscles (that is, sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles); **AND**
 - 3. There is sustained head torsion and/or tilt with limited range of motion in the neck; **AND**
 - 4. The duration of the condition must be greater than six months; **AND**
 - 5. Alternative causes of the patient's symptoms have been considered and ruled out including chronic neuroleptic treatment, [cervicogenic headaches](#), [myofascial pain syndrome](#), contractures or other [neuromuscular](#) conditions.
- B. Contraindications for use of Botulinum Toxin:
- 1. Absolute:
 - a. Inflammation or infection at the site of injection,
 - b. Allergy to the drug.
 - 2. Relative:
 - a. Inability of patient to cooperate,
 - b. Coagulopathy,
 - c. Disease of [neuromuscular](#) transmission:
 - i. Myasthenia Gravis,
 - ii. Eaton Lambert Syndrome,
 - iii. amyotrophic lateral sclerosis,
 - iv. peripheral neuropathy,
 - v. motor neuron disease,
 - d. Concurrent use of medications that affect [neuromuscular](#) transmission such as aminoglycoside antibiotics.

Policy: Botulinum Toxin Injection

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 46505, 64612, 64613, 64614, 64653, 67345, 95873, 95874, J0585, J0587, S2340, S2341

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Medical Term Definitions

Achalasia

failure to relax of the smooth muscle fibers of the gastrointestinal tract at any point of junction of one part with another.

Blepharospasm

twitching of the eyelid

Cervical Dystonia

another term for spasmodic torticollis.

Clonic

contraction/relaxation in rapid succession.

Detrusor

bundles of smooth muscle fibers forming the muscular coat of the urinary bladder which are arranged in a longitudinal and a circular layer and on contraction, serve to expel urine.

Detrusor sphincteric dyssynergia

contraction of the sphincter muscle of the urethra at the same time the detrusor muscle of the bladder is contracting, resulting in obstruction of normal urinary outflow.

Dyskinesia

distortion or impairment of voluntary movement.

Dystonia

distortion or impairment of voluntary movements due to disordered tonicity of muscle.

Frey's Syndrome

also called auriculotemporal syndrome. The appearance of a red area and of sweating on the cheek in connection with eating; seen in lesions of the parotid gland and due to some involvement of the auriculotemporal nerve.

Hemifacial spasm

spasm of muscles of one half of the face.

Policy: Botulinum Toxin Injection

Myoclonus

rapid, shock-like muscle jerks that are involuntary.

Myofascial pain syndrome

a chronic pain syndrome occurring in a region of the body, characterized by painful muscles with increased tone and stiffness containing trigger points. A trigger point is a hyperirritable spot within a taut band of skeletal muscle or muscle fascia that is painful on compression, gives rise to characteristic pain referral patterns, and may elicit a twitch in the muscle.

Neuromuscular

pertains to the nerves and the muscles.

Spasmodic

sudden violent and involuntary contractions of a muscle or group of muscles; may also involve pain and interference with function producing involuntary movement and distortion.

Spasmodic dysphonia

difficulty in speaking due to excessively vigorous adduction, or rarely abduction, of the vocal cords against each other, so that the voice is hoarse, soft, and strained.

Spasticity

increased muscle tone with heightened deep tendon reflexes.

Strabismus

deviation of the eye which the patient cannot overcome.

Tics

habitual, repeated contraction of certain muscles, resulting in stereotyped individualized actions that can be voluntarily suppressed for only brief periods, e.g., clearing of the throat, sniffing, pursing the lips, excessive blinking, etc. These tics are especially prominent when the person is under stress.

Tonic

a prolonged muscular contraction.

Torticollis

a contracted state of the cervical muscles, producing twisting of the neck and an unnatural position of the head.

Scientific Background and Reference Sources

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Policy: Botulinum Toxin Injection

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Policy: Botulinum Toxin Injection

Senior Medical Director - 9/2009

Policy Implementation/Update Information

- 8/85 Original Policy National Association - Investigational for blepharospasm
- 6/94 Evaluated: Local Policy issued covering Blepharospasm, Strabismus, Hemifacial spasm, Facial spasm, Spasmodic dysphonia, and Spasmodic torticollis. Investigational for chronic paralytic strabismus, treatment of dynamic deformity secondary to cerebral palsy.
- 4/96 Revised: Added additional covered indications and investigational indications, TEC Bulletin 2/96
- 4/97 Reaffirmed
- 5/99 Reaffirmed
- 7/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 4/2000 Statement added to section, "When Botulinum-A Toxin Injection is not covered", which says, "(1) For conditions other than those listed above." System coding changes.
- 7/00 Added Gustatory sweating (Frey's Syndrome) as a covered indication. Specialty Matched Consultant Advisory Panel.
- 9/00 Medical Policy Advisory Group review. Approved. No change in criteria.
- 10/00 Revised. Criteria changes. Botulinum now eligible for coverage for achalasia, chronic anal fissure, and investigational for headache or migraine, myofascial pain syndrome, or tremors such as benign essential tremor, chronic motor tic disorder and tics associated with Tourette syndrome. Medical Policy Advisory Group - Approved.
- 04/01 Changes in formatting.
- 10/01 Policy name changed from Botulinum A Toxin Injection. Revised description to include type B Botulinum (Myobloc) and FDA labeled indications to include cervical dystonia. System application guidelines revised.
- 3/02 System coding changes. Added code J0587 to policy and removed code J3490.
- 5/02 Revised under when it is covered, number 3. a. to include, "and/or". Codes 64612-64614, and 67345 added to Billing and Coding section.
- 8/03 Description section revised for clarity. Added spasmodic dysphonia under "When Covered" section. Added chronic low back pain under "When Not Covered" section. Reformatted "When Covered" and "When Not Covered" sections for ease of reading. Removed codes 64040 and 67399 from Billing and Coding section. Added Codes S2340 and S2341 to Billing and Coding section. Added references.
- 8/26/04 Specialty Matched Consultant Advisory Panel review. No changes to criteria. Benefits Application and Billing/Coding sections updated for consistency. Reference sources added.
- 2/17/05 Added the following statement to "When Covered" and "Policy Guidelines" sections: Refer to separate policy number MED1215, titled "Hyperhidrosis, Treatment of" regarding Botulinum toxin injection guidelines for patients with primary Hyperhidrosis. Key word added.
- 1/19/06 Added 2006 CPT codes 46505, 64653, 95873, 95874 to Billing/Coding section.
- 9/18/06 Under "When Covered" section, added "Botulinum toxin may be considered medically necessary as a treatment of incontinence due to detrusor overreactivity caused by spinal cord injury that is inadequately controlled with anticholinergic therapy." Under "When not Covered" section, 3.c. now reads "headache including migraine, chronic tension, chronic daily, and cervicodystonic head-

Policy: Botulinum Toxin Injection

- aches". Added 3.i. sialorrhea (drooling); 3.j. lateral epicondylitis; 3.k. benign prostatic hyperplasia; 3.l. detrusor overreactivity not due to spinal cord injury; 3.m. detrusor sphincteric dyssynergia. Medical term definitions added. Reference sources added.
- 6/4/07 Specialty Matched Consultant Advisory Panel review (re: urological indications) 5/2007. No changes to criteria. Reference sources added.
- 8/27/07 Under "**When Covered**" section: 1.c.- added "such as hemifacial spasm"; 1.d.- added "(see "Policy Guidelines" section for use of Botulinum Toxin for this indication)"; 2.i.- added "or to demyelinating conditions such as multiple sclerosis."; deleted 2.k. Spasmodic torticollis; 3.b.- revised to "lower esophageal achalasia where the patient has not responded to dilation therapy or where the patient is considered a poor surgical candidate." Under "**When not Covered**" section: 3.a.- end of sentence revised to "and cervicogenic or "cervicodystonic"; added 3.l. priformis syndrome. Under "**Policy Guidelines**" section: Added A.1-5: Use of Botulinum Toxin for Cervical Dystonia (Spasmodic Torticollis): **ALL** of the following criteria must be met: 1) Postural disturbance and pain must be of moderate or greater severity as documented by interference with specific activities of daily living and unresponsive to a trial of appropriate standard conservative therapy that may include non-narcotic analgesics, muscle relaxants and physical modalities; **AND** 2) There are clonic and/or tonic involuntary contractions of multiple neck muscles (that is, sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles); **AND** 3) There is sustained head torsion and/or tilt with limited range of motion in the neck; **AND** 4) The duration of the condition must be greater than six months; **AND** 5) Alternative causes of the patient's symptoms have been considered and ruled out including chronic neuroleptic treatment, cervicogenic headaches, myofascial pain syndrome, contractures or other neuromuscular conditions. Added B. Contraindications for use of Botulinum toxin: 1) Absolute: a. Inflammation or infection at the site of injection. b. Allergy to the drug. 2) Relative: a. Inability of patient to cooperate b. Coagulopathy c. Disease of neuromuscular transmission: i. Myasthenia Gravis ii. Eaton Lambert Syndrome iii. Amyotrophic lateral sclerosis iv. Peripheral neuropathy v. Motor neuron disease d. Concurrent use of medications that affect neuromuscular transmission such as aminoglycoside antibiotics. **Medical Term Definitions** added. Notification given 8/27/07. Effective date 11/5/07.
- 4/7/08 Added FDA warning information to the "Description" section; "Please note that the US Food & Drug Administration (FDA) has issued a warning regarding the use of botulinum toxin. It has been reported that there have been serious systemic adverse reactions including respiratory distress and death from botulinum toxins types A and B. The adverse events have occurred in both FDA approved and unapproved uses. Most of the adverse events have occurred in children treated for cerebral palsy associated limb spasticity. Safety, efficacy and dosage has not be established of the use of Botulinum toxins for limb spasticity of cerebral palsy or any condition in children under the age of 12. Also added the following to the "When Covered" section; **"The treating physician should carefully review the above FDA issued warning. Use of botulinum toxin for off-label indications should only be done when the treating physician has determined that the benefits of the treatment clearly outweigh the risks of the therapy."** References added.
- 7/14/08 Specialty Matched Consultant Advisory review 5/29/08. Added comment; "(See "Policy Guidelines" section for use of Botulinum Toxin for this indication)" to 3.a. under the "When Covered" section. Changed the wording in #5 under the "When Covered" section to read "either idiopathic or due to neurogenic causes" and added "multiple sclerosis" as an example. Added additional examples of non-covered indications under the "When Covered" section. These are "c. joint pain, d. mechanical neck disorders, e. neuropathic pain after neck dissection, g. pain after hemorrhoidectomy or lumpectomy, and n. interstitial cystitis." No change to policy intent. Added "Myoclonus and Tics" to "Definition" section. References added.
- 1/12/09 Revised "Description" section to add; "Type A (Botox®) is more potent and longer acting than type B (Myobloc®). Units and dosing are not equivalent and cannot be interchanged." The word "warning" was removed from the statement; "(FDA) has issued an early communication regarding an on-going safety review" and added "The FDA plans to communicate to the public its findings,

Policy: Botulinum Toxin Injection

resulting recommendations, and any regulatory actions after the review of the data are completed." Updated the "When Covered" section with the following changes;"2. dystonia/spasticity resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake)" and statement " The treating physician should carefully review the above FDA issued warning." Added additional wording for clarifications to various indications and an additional indication; "2.k.Spinal cord or traumatic brain injury;". Added additional wording for clarification to various indications in the "When Not Covered" section and "4.The use of assays to detect antibodies to botulinum toxin is considered investigational." Added "In cases for which botox has been approved in the past, medical records are required yearly to document ongoing effectiveness of botox" to the "Policy Guidelines section. References added.

10/26/09 Revised "Description" section. Added information related to the FDA approval of Dysport for cervical dystonia, new established names of Botox and Myobloc, and the FDA requirement of a boxed warning and a Risk Evaluation and Mitigation Strategy (REMS) for all Botulinum Toxin products. Changed "paraplegia" to paraparesis" in 2.e. under the "When Covered" section. Added 3.d. "Sialorrhea (drooling) associated with Parkinson disease" to the "When covered" section. Changed the wording under the "Policy Guidelines" section in A.2. from "involuntary contractions of multiple neck muscles" to "involuntary contractions of one or more neck muscles". Reviewed with the Senior Medical Director 9/16/09. References added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.