MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

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BOTULINUM TOXIN

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

A family of seven distinct toxins produced by the anaerobic organism *Clostridia botulinum*. These seven serotypes are A, B, C-1, D, E, F and G. When administered intramuscularly, all toxins prevent the release of acetycholine from nerve endings producing local paralysis and allowing individual muscles to selectively weaken. Electromyographic (EMG) guidance may be used to direct injection of botulinum toxin, especially if the esophagus or larynx is being treated.

Passive immunization with equine botulinum antitoxin may be used for military personnel who are at risk for exposure to botulinum toxin.

Some individuals who initially respond to botulinum toxin may develop a secondary nonresponse for a variety of reasons. A small percentage develops antibodies that neutralize the activity of the botulinum toxin type. Botulinum toxin antibody assays have been investigated to detect antibodies, but the assays cannot discriminate between neutralizing and non-neutralizing antibodies and, therefore, could generate false positives in some individuals.

BOTULINUM TOXIN (cont.)

Description: (cont.)

Botulinum Toxin Type A formulations include Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA) and Xeomin® (incobotulinumtoxinA). Botulinum Toxin Type B is marketed as Myobloc® (rimabotulinumtoxinB).

Following injection, effects may be seen within several days of the injection and the therapeutic effect generally last at least 12 weeks. Administration of any botulinum toxin should not occur more frequently than every 12 weeks.

Definitions:

Achalasia:
Failure to relax.

Blepharospasm:
A twitching or spasmodic contraction of the eye or eyes.

Dyskinesia:
A defect in the ability to perform voluntary movement.

Dystonia:
Prolonged muscular contractions that can cause twisting of body parts.

Schilder's Disease:
A rare disease of the pediatric central nervous system that produces brain lesions.

Spasmodic Torticollis:
A debilitating, painful neurologic disorder characterized by intermittent or sustained contractions of the muscles around the neck which control the position of the head. This causes the head to lean to one side, or to be pulled forward or backward. Spasmodic torticollis may also be referred to as cervical dystonia.

BOTULINUM TOXIN (cont.)

Criteria:

For botulinum toxin for the treatment of hyperhidrosis, see BCBSAZ Medical Coverage Guideline, *"Hyperhidrosis Treatment"*.

- **Botulinum Toxin Type A (Botox, Dysport, Xeomin) or Type B (Myobloc):**

➢ Botulinum Toxin Type A or Type B is considered ***medically necessary*** for the specific drug indicated with documentation of **ANY** of the following:

Indication	Botox	Dysport	Xeomin	Myobloc
Blepharospasm in an individual 12 years of age and older	Yes	Yes	Yes	No
Chronic anal fissure	Yes	Yes	No	No
Demyelinating diseases, e.g., multiple sclerosis, Schilder's disease	Yes	Yes	No	No

BOTULINUM TOXIN (cont.)

Criteria: (cont.)

COVERAGE FOR TREATMENT TO CORRECT A CONGENITAL DEFECT OR BIRTH ABNORMALITY IS DEPENDENT UPON BENEFIT PLAN LANGUAGE AND IS SUBJECT TO THE PROVISIONS OF THE RECONSTRUCTIVE BENEFIT AND THE COSMETIC BENEFIT EXCLUSION. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS AND THE FUNCTIONAL IMPAIRMENT REQUIREMENT.

Indication	Botox	Dysport	Xeomin	Myobloc
Dystonia resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake) and/or pain in an individual with **ANY** of the following: ▪ Focal task-specific dystonia of the upper extremities (e.g. organic writer's cramp) ▪ Laryngeal dystonia, including adductor spasmodic dysphonia and laryngeal spasm ▪ Limb dystonia ▪ Oromandibular dystonia (orofacial dyskinesia, Meige syndrome) ▪ Torsion dystonia, idiopathic (primary or genetic) or acquired (brain injury)	Yes	Yes	No	No

BOTULINUM TOXIN (cont.)

Criteria: (cont.)

Indication	Botox	Dysport	Xeomin	Myobloc
Esophageal achalasia in individuals who have not responded to dilatation therapy or are considered poor surgical risks	Yes	Yes	No	No
Facial nerve (cranial nerve VII), disorders e.g., hemifacial spasm, Bell's Palsy in an individual 12 years of age and older	Yes	Yes	Yes	No
Incontinence due to detrusor overreactivity (urge incontinence), either idiopathic or due to neurogenic causes (e.g., spinal cord injury, multiple sclerosis), that is inadequately controlled with anticholinergic therapy	Yes	Yes	No	No
Overactive Bladder (OAB) symptoms of urge urinary incontinence, urgency and frequency in adults unresponsive to or intolerant of anticholinergic therapy	Yes	No	No	Yes

BOTULINUM TOXIN (cont.)

Criteria: (cont.)

Indication	Botox	Dysport	Xeomin	Myobloc
Migraine headache, chronic Initial 6-month trial (1 treatment with retreatment in 12 weeks) for an adult with documentation of **ALL** of the following: ▪ Meet International Headache Classification (ICHD-2) diagnostic criteria for chronic migraine headache (i.e., migraine headaches lasting at least 4 hours on at least 15 days per month **AND** migraine headaches for at least 3 months) ▪ Symptoms persist despite adequate trials of at least 2 agents from different classes of medications used in the treatment of chronic migraine headaches, (e.g. tryptans, antidepressants, antihypertensives, antiepileptics) unless otherwise contraindicated. Continuation of treatment (every 12 weeks) beyond the first 6-months with documentation of **ONE** of the following: ▪ Migraine headache frequency reduced by at least 7 days per month ▪ Migraine headache duration reduced at least 100 hours per month	Yes	No	No	No

BOTULINUM TOXIN (cont.)

Criteria: (cont.)

COVERAGE FOR TREATMENT TO CORRECT A CONGENITAL DEFECT OR BIRTH ABNORMALITY IS DEPENDENT UPON BENEFIT PLAN LANGUAGE AND IS SUBJECT TO THE PROVISIONS OF THE RECONSTRUCTIVE BENEFIT AND THE COSMETIC BENEFIT EXCLUSION. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS AND THE FUNCTIONAL IMPAIRMENT REQUIREMENT.

Indication	Botox	Dysport	Xeomin	Myobloc
Sialorrhea (drooling) associated with Parkinson's disease	Yes	Yes	No	Yes
Spasmodic torticollis (cervical dystonia) for an individual 16 years of age and older to reduce the severity of abnormal head position and neck pain	Yes	Yes	Yes	Yes
Spastic conditions resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake) and/or pain in an individual with **ANY** of the following: ▪ Cerebral palsy (not specific to any age) ▪ Neuromyelitis optica ▪ Spastic hemiplegia ▪ Spastic paraplegia, hereditary ▪ Spasticity related to stroke ▪ Spinal cord or traumatic brain injuries	Yes	Yes	No	No

BOTULINUM TOXIN (cont.)

Criteria: (cont.)

Indication	Botox	Dysport	Xeomin	Myobloc
Strabismus in an individual 12 years of age and older who has failed conservative treatment and/or surgical treatment	Yes	Yes	No	No
Upper limb spasticity to decrease the severity of increased muscle tone in **ANY** of the following: ▪ Elbow flexors (biceps) ▪ Finger flexors (flexor digitorum profundus and flexor digitorum sublimis) ▪ Wrist flexors (flexor carpi radialis and flexor carpi ulnaris)	Yes	Yes	Yes only if related to stroke	No

The Prescribing Information states the following when referring to pediatric use:

Botox: Safety and efficacy established for blepharospasm and strabismus is 12 years and older
Safety and efficacy established for cervical dystonia is 16 years and older
Safety and efficacy established for other conditions is 18 years and older
Dysport: Safety and efficacy established for is 18 years and older
Xeomin: Safety and efficacy established for 18 years and older
Myobloc: Safety and effectiveness HAS NOT been established for pediatric patients (no age provided)

BOTULINUM TOXIN (cont.)

Criteria: (cont.)

Botulinum Toxin Type A (Botox, Dysport, Xeomin) or Type B (Myobloc): (cont.)

- Botox, Dysport, Xeomin or Myobloc for the treatment of wrinkles is considered ***cosmetic*** *and* ***not eligible for coverage,*** even when the procedure will improve emotional, psychological or mental condition or performance, based upon **ANY** of the following:

  1. Intent to enhance or improve appearance
  2. Absence of a functional physical impairment

- Botox, Dysport, Xeomin or Myobloc for all other indications not previously listed is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These conditions include, *but are not limited to:*

  - Benign prostatic hyperplasia
  - Detrusor sphincter dyssynergia (after spinal cord injury)
  - Facial wound healing
  - Gastroparesis
  - Headaches, including chronic daily headache, tension headache, and migraine headache not meeting criteria listed above
  - Hirschprung's disease
  - Internal anal sphincter (IAS) achalasia
  - Interstitial cystitis
  - Joint pain
  - Lateral or medial epicondylitis
  - Low back pain, chronic
  - Mechanical neck disorders
  - Muscle spasm
  - Myofascial pain syndrome
  - Neuropathic pain after neck dissection
  - Post-hemorrhoidectomy pain
  - Post-lumpectomy pain
  - Prevention of pain associated with breast reconstruction
  - Sialorrhea (drooling) that is not associated with Parkinson’s disease
  - Tinnitus
  - Tremors, e.g., benign essential tremor
  - Tics associated with Tourette’s syndrome and chronic motor tic disorder

BOTULINUM TOXIN (cont.)

Criteria: (cont.)

Equine Botulinum Antitoxin:

- Immunization with equine botulinum antitoxin for an individual at high risk for exposure to botulinum toxin is ***eligible for coverage*** when the claim is submitted by a military facility.

- Immunization with equine botulinum antitoxin for all other indications not previously listed is considered ***not medically necessary*** and ***not eligible for coverage***.

Botulinum Toxin Antibodies:

- Assays to detect antibodies to botulinum toxin are considered ***experimental or investigational*** based upon:

    1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
    2. Insufficient evidence to support improvement of the net health outcome, and
    3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
    4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

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15. Drug Facts & Comparisons. Botulinum Toxin Type B (Myobloc). Accessed 10/2013.

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BOTULINUM TOXIN (cont.)

Resources: (cont.)

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BOTULINUM TOXIN (cont.)

Resources: (cont.)

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FDA Product Approval Information for Botox® (onabotulinumtoxinA):

- FDA-approved indication: For the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.

  For the treatment of cervical dystonia in adults* to reduce the severity of abnormal head position and neck pain associated cervical dystonia (also referred to as spasmodic torticollis).

  For the treatment of 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).

  Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).

  For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

  For the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., SCI, MS) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

FDA Product Approval Information for Botox® Cosmetic (onabotulinumtoxinA):

- FDA-approved indication: For the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

  For the temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients.

BOTULINUM TOXIN (cont.)

Resources: (cont.)

FDA Product Approval Information for Dysport® (abobotulinumtoxinA):

- FDA-approved indication: For 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.

  For the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age.

FDA Product Approval Information for Xeomin® (incobotulinumtoxinA):

- FDA-approved indication: For the treatment of adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naive and previously treated patients (also referred to as spasmodic torticollis).

  For the treatment of blepharospasm in adults previously treated with onabotulinumtoxinA (Botox).

  For the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

FDA Product Approval Information for Myobloc® (rimabotulinumtoxinB):

- FDA-approved indication: For the treatment of adult patients ** with cervical dystonia to reduce the severity of abnormal head position and neck pain associated cervical dystonia (also referred to as spasmodic torticollis).

* FDA defines "pediatric patients" as "the pediatric age group, from birth to sixteen years".

** The safety and efficacy in pediatric patients have not been established.