BOTULINUM TOXIN

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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**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 acetylcholine 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.
BOTULINUM TOXIN (cont.)

Description: (cont.)

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

Definitions:

Preferred Botulinum Toxin Injections:
▪ Botox
▪ Dysport

Non-Preferred Botulinum Toxin Injections:
▪ Xeomin
▪ Myobloc

Adult:
Age 18 years and older

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.
BOTULINUM TOXIN (cont.)

Definitions: (cont.)

Significant Adverse Drug Event:
A significant adverse drug event occurs when an individual’s outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals’ body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

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.

Criteria:

For botulinum toxin for the treatment of hyperhidrosis, see BCBSAZ Medical Coverage Guideline, #O420, “Hyperhidrosis Treatment”.

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

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.

- Botulinum Toxin Type A or Type B is considered medically necessary with documentation of ALL of the following:
  1. Absence of ALL of the following contraindications:
     - Hypersensitive to any botulinum toxin preparation or to any of the components in the formulation
     - Infection at the proposed injection site(s)
  2. Failed response to preferred botulinum toxin therapy medications Botox AND Dysport (refer to table listed on pages 4-7 for uses) with documentation of ANY of the following:
     - Individual’s condition has not improved or has worsened
     - Individual experienced a significant adverse drug event to the preferred medications
     - Individual is intolerant to the preferred medications
     - Individual has contraindications to the preferred medications
### BOTULINUM TOXIN (cont.)

**Criteria:** (cont.)

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

- Botulinum Toxin Type A or Type B is considered *medically necessary* with documentation of ALL of the following: (cont.)

  3. **ANY** of the following according to limitations shown:

<table>
<thead>
<tr>
<th>Administration of any botulinum toxin should not occur more frequently than every 12 weeks.</th>
<th>Uses</th>
<th>Botox</th>
<th>Dysport</th>
<th>Xeomin</th>
<th>Myobloc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blepharospasm in an individual 12 years of age and older</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Chronic anal fissure</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Demyelinating diseases, e.g., multiple sclerosis, Schilder’s disease.</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Dystonia resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake) and/or pain in an individual with ANY of the following:</td>
<td>Botox</td>
<td>Dysport</td>
<td>Xeomin</td>
<td>Myobloc</td>
<td></td>
</tr>
<tr>
<td>• Focal task-specific dystonia of the upper extremities (e.g., organic writer’s cramp)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Laryngeal dystonia, including adductor spasmodic dysphonia and laryngeal spasm.</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Limb dystonia</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Oromandibular dystonia (orofacial dyskinesia, Meige syndrome)</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Torsion dystonia, idiopathic (primary or genetic) or acquired (brain injury).</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Esophageal achalasia in individuals who have not responded to dilatation therapy or are considered poor surgical risks</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Facial nerve (cranial nerve VII), disorders e.g., hemifacial spasm, Bell’s Palsy in an individual 12 years of age and older</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Incontinence due to detrusor overactivity (urge incontinence), either idiopathic or due to neurogenic causes (e.g., spinal cord injury, multiple sclerosis), that is inadequately controlled with anticholinergic therapy</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Overactive Bladder (OAB) symptoms of urge urinary incontinence, urgency and frequency in adults unresponsive to or intolerant of anticholinergic therapy</td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Botulinum Toxin (cont.)

**Criteria:** (cont.)

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

- Botulinum Toxin Type A or Type B is considered *medically necessary* with documentation of **ALL** of the following: (cont.)

3. **ANY** of the following according to limitations shown: (cont.)

<table>
<thead>
<tr>
<th>Administration of any botulinum toxin should not occur more frequently than every 12 weeks.</th>
<th><strong>Uses</strong></th>
<th>Botox</th>
<th>Dysport</th>
<th>Xeomin</th>
<th>Myobloc</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Migraine headache, chronic</strong></td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>- Initial 6-month trial (1 treatment with retreatment in 12 weeks) for an adult with documentation of <strong>ALL</strong> of the following:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Meet International Headache Classification of Headache Disorders (ICHD-3) diagnostic criteria for chronic migraine headache. (i.e., migraine headaches on at least 15 days per month <strong>AND</strong> migraine headaches for at least 3 months <strong>AND</strong> features of migraine headache on at least 8 days. Features of migraine headache include: Lasts 4-72 hours <strong>AND</strong> has at least 2 of the following 4 characteristics: unilateral, pulsating, moderate or severe pain intensity, aggravates or causes avoidance of routine physical activity <strong>AND</strong> associated with at least one of the following during the headache: Nausea and/or vomiting or photophobia and phonophobia.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 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.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Continuation of treatment (every 12 weeks) beyond the first 6-months with documentation of <strong>ONE</strong> of the following:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Migraine headache frequency reduced by at least 7 days per month</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Migraine headache duration reduced at least 100 hours per month</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sialorrhea (drooling) associated with Parkinson’s disease</strong></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Spasmodic torticollis (cervical dystonia) for an individual 16 years of age and older to reduce the severity of abnormal head position and neck pain</strong></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
**BOTULINUM TOXIN (cont.)**

**Criteria: (cont.)**

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

- Botulinum Toxin Type A or Type B is considered *medically necessary* with documentation of **ALL** of the following: (cont.)

  3. **ANY** of the following according to limitations shown: (cont.)

<table>
<thead>
<tr>
<th>Administration of any botulinum toxin should not occur more frequently than every 12 weeks.</th>
<th>Botox</th>
<th>Dysport</th>
<th>Xeomin</th>
<th>Myobloc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spastic conditions resulting in functional impairment (interference with joint function, mobility, communication, nutritional intake) and/or pain in an individual with <strong>ANY</strong> of the following:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Cerebral palsy (not specific to any age)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>▪ Neuromyelitis optica</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>▪ Spastic hemiplegia</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>▪ Spastic paraplegia, hereditary</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>▪ Spasticity related to stroke</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>▪ Spinal cord or traumatic brain injuries</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Strabismus in an individual 12 years of age and older who has failed conservative treatment and/or surgical treatment</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Upper limb spasticity to decrease the severity of increased muscle tone in <strong>ANY</strong> of the following:</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>▪ Elbow flexors (biceps)¹</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>▪ Finger flexors (flexor digitorum profundus and flexor digitorum sublimis)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>▪ Wrist flexors (flexor carpi radialis and flexor carpi ulnaris)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>¹ Xeomin also indicated for elbow flexors (brachioradialis and brachialis)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Upper limb spasticity to decrease the severity of increased muscle tone in thumb flexors (adductor pollicis and flexor pollicis longus)</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Upper limb spasticity to decrease the severity of increased muscle tone in <strong>ANY</strong> of the following:</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>▪ Clenched fist (flexor digitorum superficialis and flexor digitorum profundus)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>▪ Forearm pronators (pronator quadratus and pronator teres)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>▪ Thumb-in-palm (Flexor pollicis longus, adductor pollicis and Flexor pollicis brevis/opponens pollicis)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
BOTULINUM TOXIN (cont.)

Criteria: (cont.)

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

- Botulinum Toxin Type A or Type B is considered *medically necessary* with documentation of ALL of the following: (cont.)

  3. **ANY** of the following according to limitations shown: (cont.)

<table>
<thead>
<tr>
<th>Administration of any botulinum toxin should not occur more frequently than every 12 weeks.</th>
<th>Botox</th>
<th>Dysport</th>
<th>Xeomin</th>
<th>Myobloc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower limb spasticity to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lower limb spasticity in pediatrics 2 years of age and older (gastrocnemius, soleus)</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

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 lower limb spasticity in pediatrics 2-18 years of age only and in adults 18 years and older for other uses
- Myobloc: Safety and effectiveness HAS NOT been established for pediatric patients (no age provided)
- Xeomin: Safety and efficacy established for 18 years and older

- 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
BOTULINUM TOXIN (cont.)

Criteria: (cont.)

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

- Botox, Dysport, Xeomin or Myobloc for all other uses not previously listed or if above criteria not met 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 uses include, but are not limited to:

- Benign prostatic hyperplasia
- Depression
- 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
- Sialorrhea (drooling) that is not associated with Parkinson’s disease
- Temporomandibular joint disorders
- Tics associated with Tourette’s syndrome and chronic motor tic disorder
- Tinnitus
- Tremors, e.g., benign essential tremor
- Trigeminal Neuralgia
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 uses 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:

Literature reviewed 11/28/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


BOTULINUM TOXIN (cont.)

Resources: (cont.)


BOTULINUM TOXIN (cont.)

Resources: (cont.)


26. FDA. Prescribing Information: Botulinum Toxin Type A Dysport. Accessed 06/14/17, 05/11/17, 06/19/16, 11/19/2015, 10/2013.

27. FDA. Prescribing Information: Botulinum Toxin Type A Xeomin. Accessed 05/11/17, 06/19/16, 11/19/2015, 10/2013.


BOTULINUM TOxin (cont.)

Resources: (cont.)


39. Mathew, NT, Kailasarn, J, al e. Disease Modification in Chronic Migraine With Botulinum Toxin Type A Long Term Experience.


BOTULINUM TOXIN (cont.)

Resources: (cont.)


BOTULINUM TOXIN (cont.)

Resources: (cont.)


59. Troost, T, Rosenberg, JR, Wiles, R. Improvement in Intractable Headache With Repeated Botulinum Toxin Type A Treatment.60(5 Supl 1:A323-4 (1 pg)):P04 153.


BOTULINUM TOXIN (cont.)

Resources: (cont.)

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), and thumb flexors (adductor pollicis and flexor pollicis longus).

  For the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

  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.
BOTULINUM TOxin (cont.)

Resources: (cont.)

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.

FDA Product Approval Information for Dysport® (abobotulinumtoxinA):

- FDA-approved indication: For the treatment of adults with cervical dystonia.

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.

For the treatment of spasticity in adult patients.

For the treatment of lower limb spasticity in pediatric patients 2 years of age and older.

FDA Product Approval Information for Xeomin® (incobotulinumtoxinA):

- FDA-approved indication: For the treatment of upper limb spasticity in adult patients.

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.
BOTULINUM TOXIN (cont.)

Resources: (cont.)

FDA Product Approval Information for Myobloc® (rimabotulinumtoxinB):

- FDA-approved indication: For the treatment of adult patients ¹ with cervical dystonia to reduce the severity of abnormal head position and neck pain associated cervical dystonia (also referred to as spasmodic torticollis).

¹ The safety and efficacy in pediatric patients have not been established.
BOTULINUM TOXIN (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’ é atah nilíngíí Blue Cross Blue Shield of Arizona haada yit’éegó bina’idí̱ldíkgó éí doodago Háída bíjá aníyeedííí t’áadoo le’ é yina’idí̱ldíkgó bee hazh’áńní hólq díí t’áá hazaad’ehíí háká a’doowolgo bee haz’hí doo báq̲h ilínígóó. Ata’ halné’ígíí kojí’ bič’i’ hodílíníí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Đê nói chuyện với một thống dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص يسعده أسلحة بخصوص الضروريه بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.
BOTULINUM TOXIN (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyang tinutuuanan, ay maaaring magkarantangan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuhang tungkol at impormasyon sa iyang wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 원할 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

انگلیسی: اگر شما یا کسی که شما به آن کمک می‌کنید، سوالاتی در مورد Blue Cross Blue Shield of Arizona داشته باشید، حق ارائه آن‌ها به شما در زبان خود را به طور رایگان دریافت می‌نماید.

Assyrian:

Elam: Blue Cross Blue Shield of Arizona بایک، یک یا کسی که شما به آن کمک می‌کنید، سوالاتی در مورد Blue Cross Blue Shield of Arizona داشته باشید، حق ارائه آن‌ها به شما در زبان خود را به طور رایگان دریافت می‌نماید.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodioce, nazovite 877-475-4799.

Thai: หากคุณ หรือคุณช่วยเหลือผู้อื่นถามคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ขอรับความช่วยเหลือและข้อมูลในภาษาที่คุณต้องการ ที่สายด่วน 877-475-4799