**Medical Coverage Policy**

**Botulinum Toxin Injection**

- **Device/Equipment**
- **Drug**
- **Medical**
- **Surgery**
- **Test**
- **Other**

**Effective Date:** 9/17/2007  
**Policy Last Updated:** 8/7/2012

- **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

- **Prospective review is not required.**

**Description:**

Botulinum toxin is a sterile lyophilized form of purified botulinum toxin produced by the anaerobic clostridium botulinum. There are seven distinct serotypes designated as type A, B, C-1, D, E, F, and G. Only type A and type B preparations are available in this country. It is one of the most poisonous of all biological substances. It is the mechanism of action making botulinum toxin so dangerous which also provides the foundation for it to be considered a therapeutic substance. When injected at therapeutic doses, it produces a localized chemical denervation muscle paralysis.

The paralytic effect on muscles injected with botulinum toxin type A is useful in reducing the excessive, abnormal contractions associated with blepharospasm. This drug has been FDA-approved for strabismus, blepharospasm associated with dystonia, including benign essential blepharospasm, or nerve disorders in patients over 12 years of age and cervical dystonia in adults. Botulinum toxin is used for disorders of both spasticity and dystonia. Dystonia is a general term describing a state of abnormal or disordered tonicity of muscle. Spasticity is a subset of dystonia, describing a velocity-dependent increase in tonic-stretch reflexes with exaggerated tendon jerks. Spasticity is a common feature of injuries to the central nervous system. Other uses not yet FDA-approved have been used in the physician community and are accepted practice for the treatment of many conditions, all associated with dystonia. Botulinum type B currently has FDA approval for cervical dystonia and Botox (onabotulinumtoxinA) for the prevention of chronic migraine. Chronic migraine is defined as episodes that otherwise meet criteria for migraine (e.g., at least 4 hours in duration) that occur on at least 15 days per month for more than 3 months, in the absence of medication overuse. A recent review of botulinum toxin for episodic migraines (fewer than 15 episodes per month) which, in a pooled analysis of available data from RCTs, found no significant differences between the botulinum toxin A and placebo groups in change in the number of migraines per month.1

The International Headache Classification (ICD-2) (ihs-classification.org/en/), diagnostic criteria for migraine without aura are:

A. At least 5 attacks fulfilling criteria B-D  
B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)  
C. Headache has at least two of the following characteristics:
   1. unilateral location  
   2. pulsating quality  
   3. moderate or severe pain intensity  
   4. aggravation by or causing avoidance of routine activity (e.g., walking or climbing stairs)  
D. During at least one of the following:
   1. nausea and/or vomiting  
   2. photophobia and phonophobia
E. Not attributed to another disorder

On October 15, 2010, the FDA approved Botox injection for prevention of chronic migraine. Chronic migraine is defined as episodes that otherwise meet criteria for migraine (e.g., at least 4 hours in duration) that occur on at least 15 days per month for more than 3 months, in the absence of medication overuse.

Medical Criteria:
Preauthorization is required for BlueCHIP for Medicare members and recommended for all other members for the use of botulinum toxin (A or B) in the treatment of migraines:
  Prevention (treatment) of chronic migraine headache in the following situations:
  o Initial 6-month trial: Adult patients who:
    1. meet International Headache Classification (ICHD-2) diagnostic criteria for chronic migraine headache (e.g. migraine headaches lasting at least 4 hours on at least 15 days per month; migraine headaches for at least 3 months in the absence of medication overuse); and
    2. have symptoms that persist despite adequate trials of at least 2 agents from different classes of medications used in the treatment of chronic migraine headaches, e.g. antidepressants, antihypertensives and antiepileptics. Patients who have contraindications to preventive medications are not required to undergo a trial of these agents.
  o Continuing treatment beyond 6-months:
    1. Migraine headache frequency reduced by at least 7 days per month, or
    2. Migraine headache duration reduced at least 100 hours per month.

Chronic migraine is defined as migraine attacks that meet the above criteria and occur on at least 15 days/month for at least 3 months, provided there is no medication overuse.

- Migraine (346.01-346.93)

Botulinum toxin type A may be considered medically necessary (no prospective review required) in the treatment of the following conditions:

FDA-labeled indications of:

- Strabismus (378.00-378.9)
- Blepharospasm (333.81)
- Facial nerve VII disorders (351.8)
- Spasmodic torticollis (333.83)

Off-label, but for consideration as medically necessary indications for treatment of spasticity or dystonia resulting in significant functional impairment and/or pain with any of the following:

- Torsion dystonia (idiopathic and symptomatic) (333.6);
- Symptomatic torsion dystonia (333.7);
- Orofacial dyskinesia (333.82);
- Organic writer's cramp (333.84);
- Other fragments of torsion dystonia (333.89);
- Hereditary spastic paraplegia (334.1);
- Multiple sclerosis (340);
- Neuromyelitis optica (341.0);
- Schilder's disease (341.1);
- Other demyelinating diseases of central nervous system (341.8);
- Demyelinating disease of central nervous system, unspecified (341.9);
- Spastic hemiplegia affecting unspecified side (342.10);
- Spastic hemiplegia (342.11, 342.12);
- Infantile cerebral palsy (343.0-343.9);
- Quadriplegia unspecified (344.00-344.09);
- Paraplegia (344.1);
- Siplegia of upper limbs (344.2);
- Monoplegia of lower limb (344.30-344.32);
- Monoplegia of upper limb (344.40-344.42);
- Unspecified monoplegia (344.5);
- Laryngeal spasm (478.75, 478.79);
- Achalasia of lower esophageal sphincter (only if poor surgical candidate or non-responsive to dilation therapy) (530.0);
- Anal spasm (564.6);
- Anal fissure (565.0);
- Torticollis, unspecified (723.5);
- Muscle spasm (728.85);
- Other musculoskeletal symptoms referable to limbs (729.89);
- Voice disturbance (784.40-784.41, 784.49);
- Urinary Incontinence (788.30-788.39)*
- Upper limb spasticity (342.10, 342.11, 343.12);
- Equinus foot, if related to cerebral palsy (736.72);
- Spasticity related to stroke or spinal cord injury/Other forms of upper motor neuron spasticity (342.1, 342.10, 342.11, 342.12)

*The use of botulinum toxin may be considered medically necessary as a treatment of incontinence related detrusor over reactivity and incontinence of neurogenic origin (i.e., spinal cord injury, multiple sclerosis) after treatment has proven that it cannot be adequately controlled with anticholinergic therapy.

Botulinum Type B is limited to:
- Cervical dystonia (333.83);
- Congenital musculoskeletal deformities of sternocleidomastoid muscle (754.1).

**Policy:**
Coverage is provided for the botulinum toxin A and B injection when the above indications of medical necessity have been met.
Botulinum Toxin A or B is considered not medically necessary for the following due to lack of peer-review literature to support the treatment efficacy:
- Chronic motor tic disorder and tics associated with de la Tourette syndrome;
- Irritable colon;
- Biliary dyskinesia;
- Any other condition not listed in this policy.

Botox used as a treatment for winkles or any other cosmetic indication is not a covered benefit.

Reimbursement is provided only for the portion of medication used for a patient's treatment. Reimbursement is not provided for any wastage or unused portion. If a vial is divided between two patients, the billing must be for the exact amount of botulinum toxin used on each individual patient.

**Limitations of coverage:**
The appropriate injection/ destruction codes (e.g., 64612*; 64613; 67345) may be submitted in conjunction with J0585, J0586, and J0587. Reimbursement for the injection code will be on a one time basis only,
per operative session, regardless of the number of injections unless the procedure is bilateral or more than one body region is injected.

Electromyographic guidance (CPT codes 95860; 95861; 95869; 92265) may be used to ensure the proper needle location within the muscle. Again, only one unit of EMG service may be submitted per session unless the procedure is bilateral or more than one body region is being treated. Cost for special syringes is considered part of the surgical procedure and not separately reimbursable.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Member Certificate, Subscriber Agreement, and Benefits Booklet for applicable physician office injection coverage/benefits.

Botulinum toxin is covered under the member's medical benefit and is subject to any applicable copay/coinsurance and/or deductible.

Specialty Pharmacy
Botulinum toxin is available for member purchase at community pharmacies; however physicians may order Botulinum Toxin through the network specialty pharmacy. For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

Coding:
The following codes require preauthorization:
J0585
J0586
J0587
J0588

The codes listed below are covered when administration of the above drugs meets our medical criteria:
64611
64612
64613
64614
64615  (code effective January 1, 2013)
64650
67345

NOTE: If fewer than 4 salivary glands are injected, code 64611 is reported with modifier -52 to signify reduced service. When filed bilaterally, 94612 must be filed with modifier -50.

S2340
S2341

Related topics
Not applicable

Published
Policy Update, November 2000
Policy Update, May 2001
Policy Update, October 2001
Policy Update, November 2006
References:


MYOBLOC Injectable Solution (package insert). South San Francisco, CA; Elan Pharmaceuticals; December 2000.

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