

**MVP/Preferred Care BENEFIT INTERPRETATION**  
Botulinum Toxin Treatment

**Type of Policy**

Medical

**Codes**

**HCPCS:** J0585 (botulism toxin Type A)

**HCPCS:** J0587 (botulism toxin Type B)

**ICD-9 Procedure Code:** 99.29

**Evidence Basis for Policy**

**Some Proven Benefit.** This rating indicates that there are reasonably good data to support its use in the cited application(s). Further research is required to clarify clinical indications, contraindications, dosage/duration, and comparison with alternative technologies and/or impact on clinical outcomes.

**Description**

Injections of botulinum toxin (BTX-A, BTX-B, BOTOX®, and others) are an effective treatment used to improve posturing/symptoms for patients suffering from muscle spasms associated with neurological disorders. The injections weaken abnormally contracting muscles through its graded paralytic action. This is only a temporary effect and repeated injections are required to maintain the beneficial effects. Botulinum neurotoxins act to block neuromuscular transmission by binding to motor nerve terminals and inhibit the release of acetylcholine.

**Indications/Criteria**

Treatment with BTX-A or BTX-B will be considered for the following conditions:

1) Neuromuscular:

- extrapyramidal disease and abnormal movement disorders (including dystonia);
- spasmodic torticollis;
- hereditary spastic paraplegia;
- demyelinating diseases of the central nervous system, including Multiple Sclerosis;
- spastic hemiplegia;
- cerebral palsy (in those who do not have substantial fixed contractures);
- paralytic syndromes (including monoplegia, quadriplegia and quadriparesis);
- VII nerve disorders (hemifacial spasms); or,
- spasm of muscles.

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Deleted: Botulinum Toxin Type A achieves this inhibition by cleaving SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings. Botulinum Toxin Type B has been specifically demonstrated to cleave synaptic Vesicle Associated Membrane Protein (VAMP< also known as synaptobrevin) which is a component of the protein complex responsible for the docking and fusion of the synaptic vesicle to the presynaptic mem... [1]

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Deleted: logic/Musculoskeletal Indications

Deleted: <#>strabismus associated with dystonia, (378.00-378.08, (... [3]

Deleted: <#>VII nerve disorders (hemifacial spasms) (351.8);¶

Deleted: <#>Cerebral Palsy;¶ <#>spasmodic torticollis (333.8... [4]

Deleted: spastic hemiplegia (342.11); or¶

Deleted: (333.6, 333.7, 333.71,333.79, 333.82, 333.83 (... [5]

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Deleted: 333.83, 723.5, 754.1, 767.8, 300.11, 306.0, 714.0,

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Deleted: <#>spasm of muscle (728.85).¶ (... [7]

Deleted: 1, 334.2;

Deleted: <#>monoplegia of limb (334.30-344.32, 344.40-344.42 (... [8]

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Deleted: other demyelinating diseases of the central nervous (... [9]

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Deleted: quadriplegia and quadriparesis (344.00-344.09);

Deleted: other facial nerve disorders (351.8);

Deleted: (351.8);

Deleted: (728.85).

2) Ophthalmologic

- blepharospasm;
- ~~enophthalmos~~; or
- strabismus (including esotropia, exotropia, heterotropia).

3) Otolaryngologic

- Sialorrhea due to conditions such as motor neuron disease of Parkinson's Disease in those members who have failed to respond to a reasonable trial of traditional therapies (i.e., anticholinergics, speech therapy, surgical therapy) or who have a contraindication to traditional therapy; or
- laryngeal spasm.

4) Gastrointestinal

- Achalasia as alternative treatment for members who meet one of the following criteria:
  - have multiple medical problems or elderly >65 years of age making them high-risk candidates for pneumatic dilation or surgical myotomy;
  - have had a previous dilation-induced perforation; or
  - have an epiphrenic diverticulum or hiatal hernia both of which increase the risk of dilation-induced perforation;
- anal spasm; or
- anal stricture.

5) Dermatologic

- Axillary hyperhidrosis (see MVP/Preferred Care Hyperhidrosis policy)

6) Urologic

- Urinary incontinence due to neurogenic bladder after documented failure of medical therapy.

Members treated with Botulinum Toxin Type A and B must have a functional impairment associated with the dystonia or spasticity being treated.

Botulinum Toxin Type A and B injections will be considered as a possible treatment only after the member has received and been unresponsive to conventional methods of treatment. These include medication, physical therapy and other appropriate methods to control and/or treat the conditions.

Botulinum toxin treatment *is usually allowed only in the office setting*. Documentation of the condition must be submitted indicating the diagnosis and functional impairment.

*\*Requests for treatment in an outpatient setting require documentation supporting the medical necessity.*

Medications covered under the prescription drug rider are subject to the formulary listing and applicable co-payments.

Deleted: Indications

Deleted: extra ocular muscle palsy

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Deleted: Respiratory System/laryngeal dystonia (478.75);¶

Deleted: laryngeal spasm;

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Deleted: (596.54)

Deleted: Headaches (migraine, cervicogenic, tension type);¶  
 Botulinum toxin (Botox A) for use in migraine, cervicogenic or tension type headaches is allowed only in the office setting and may be considered for the following;¶  
 diagnosis is intractable migraine or status migrainous (346.90, 346.91; or cervicogenic; or tension-type headaches (307.81);¶  
 must be ordered by a participating neurologist;¶  
 submitted medical information documents failed standard medical treatments: ; or¶  
 Botulinum Toxin A injections for refractory migraine headaches will be considered when recommended by a neurologist when ALL the criteria are met:¶  
 intractable migraine headaches (with or without aura) at least two (2) times per month causing disability (absenteeism, ED visits) lasting three (3) or more days; AND¶  
 chronic headaches defined as individuals experiencing more than 15 days of headaches per month causing disability lasting three (3) or more days; AND ¶  
 failure of at least three preventive pharmacologic migraine therapies (beta-blockers, calcium channel blockers, anticonvulsants, and antidepressants) after titration to maximal tolerated doses; AND¶  
 use of rescue drugs two times/week (e.g. triptans, ergots, and non-specific analgesics

Deleted: Other

There will be no retroactive approvals.

### Exclusions/Limitations

- Botulinum Toxin Type A and B Injections are not covered for conditions other than those listed in the Indications/Criteria section of the policy.
- Additional Botulinum Toxin Type A and B injections may not be covered if two treatments in a row, utilizing an appropriate or maximum dose of medication, failed to produce a satisfactory clinical response.
- Coverage will be limited to four (4) treatments (injections)/per year and the injection code must be for a single unit of service, operative session, regardless of the number of injections performed (unless the procedure is bilateral or more than one body region is injected **and the limit would be four (4) treatments/injections/per year/per body region or site**).
- The use of Botulinum Toxin for the treatment of cosmetic issues, including facial wrinkles and frown lines, is considered not medically necessary and will not be covered.
- Botulinum Toxin Type A and B injections for the following conditions lack controlled clinical trials or are still under investigation and, therefore, are not a covered benefit:
  - detrusor-sphincter dysynergia (urinary sphincter spasm with bladder contractions following spinal cord injury);
  - stuttering and vocal tremor;
  - management of tics;
  - headaches; tension type, cervicogenic, and migraine headaches;
  - myofascial pain;
  - Parkinson's disease;
  - low back pain;
  - irritable bowel syndrome;
  - biliary dyskinesia;
  - neck pain not related to above noted indications; and
  - tremors.

**Deleted:** Botulinum Toxin Type A and B injections, for the treatment of cerebral palsy, are not indicated for members:¶  
who are beginning treatment at <18 months of age or >8 years of age; (. Requests received for ages not within this age range will require additional medical information and review by the Medical Director). ¶  
with severe fixed contractures; or¶  
with diffuse hypertonia.¶

**Deleted:** other than refractory

**Deleted:** Additional Botulinum Toxin Type A and B injections may not be covered if two treatments in a row, utilizing an appropriate or maximum dose of medication, failed to produce a satisfactory clinical response.¶  
Botulinum Toxin Type A and B injections, given at intervals < three (3) months (90 days), for the same muscle group, are not covered.

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¶  
**CMS Variation**¶  
¶  
Botulinum toxin is not covered for the following conditions:¶  
migraine headaches. Medications covered under the prescription drug rider are subject to the formulary listing and applicable co-

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**Approval(s) & Review/Revision(s)**

Medical:

Review:

Medical Advisory Team: 2/28/08

Approval:

Quality Improvement Committee: 5/12/08

Prior Approval Date: 4/10/06

Last Revision Date: 1/18/08

Origination Date: 12/98

Effective Date: 8/1/08

**Note:** For Preferred Care authorization requirements refer to Appendix A and Appendix B in the Referral/Prior Authorization/Notification Administrative Policy. You may also refer to the "Prior Authorization of Certain Prescription Drugs" for information on drugs that require prior authorization. Both policies are available on the *easyLink* for Providers at [www.preferredcare.org](http://www.preferredcare.org).

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Botulinum Toxin Type A achieves this inhibition by cleaving SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings. Botulinum Toxin Type B has been specifically demonstrated to cleave synaptic Vesicle Associated Membrane Protein (VAMP< also known as synaptobrevin) which is a component of the protein complex responsible for the docking and fusion of the synaptic vesicle to the presynaptic membrane, a necessary step to acetylcholine (neurotransmitter) release.

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Treatment is considered for the following conditions in patients 12 years of age or older.

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strabismus associated with dystonia, (378.00-378.08, 378.10-378.18) not congenital (378.9);  
blepharospasm associated with cervical dystonia (333.81);  
benign essential blepharospasm (333.81);

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Cerebral Palsy;  
spasmodic torticollis (333.83, 723.5, 754.1, 767.8, 300.11, 306.0, 714.0, 847.0);

Page 1: [5] Deleted lds 1/18/2008 8:35:00 AM

(333.6, 333.7, 333.71, 333.79, 333.82, 333.83, 333.84, 333.89)

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dystonia; (333.6, 333.79, 333.89);  
athetoid cerebral palsy (333.71)  
oromandibular dystonia (333.82);

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spasm of muscle (728.85).  
writer's cramp (333.84);

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monoplegia of limb (334.30-344.32, 344.40-344.42);  
Multiple Sclerosis ;  
neuromyelolitis optica; (341.0);  
schilder's disease; (341.1);  
spastic hemiplegia; (342.1);

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other demyelinating diseases of the central nervous system (341.9);

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(344.00-344.09, 344.1, 344.2, 344.30-344.32, 344.40-344.42 );