

MVP/Preferred Care BENEFIT INTERPRETATION MANUAL

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 continue the beneficial effects.

Indications/Criteria

Treatment is considered for the following conditions in patients 12 years of age or older. The following diagnoses are approved indications for BTX-A:

- 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);
- VII nerve disorders (hemifacial spasms) (351.8);
- Cerebral Palsy;
- spasmodic torticollis (723.5, 754.1, 767.8, 300.11, 306.0, 714.0, 847.0);
- spastic hemiplegia (342.11); or

- Cerebral Palsy (343.0, 343.3, 343.8, 343.9).

Other diagnoses that are allowed for treatment with Botox A include the following:

Nervous System and Sense Organs:

- limb dystonia (333.6);
- idiopathic torsion dystonia; (333.6);
- symptomatic torsion dystonia; (333.7);
- oromandibular dystonia (333.82);
- cervical dystonia (333.83);
- spasmodic torticollis (333.83);
- writer's cramp (333.84);
- fragments of torsion dystonia (333.89);
- hereditary spastic paraplegia; (334.1, 334.2);
- monoplegia of limb (334.30-344.32, 344.40-344.42);
- Multiple Sclerosis (340);
- neuromyelolitis optica; (341.0);
- schilder's disease; (341.1);
- spastic hemiplegia; (342.1);
- adductor spasticity;
- other demyelinating diseases of the central nervous system (341.9);
- infantile cerebral palsy (343.0, 343.1, 343.2, 343.3, 343.3, 343.4, 343.8, 343.9);
- quadriplegia and quadriparesis (344.00-344.09);
- refractory migraine headaches (346.9);
- other facial nerve disorders (351.8);
- extra ocular muscle palsy (376.5x);
- estropia (378.00-378.08, 378.10-378.18, 378.20-378.24);
- hypertropia (378.30-378.32);
- cyclotropia (378.33);
- monofixation syndrome (378.34);
- accommodative component in estropia (378.40);
- esophoria (378.41);
- exophoria (378.42);
- vertical heterophoria (378.43);
- cyclophoria (378.44);
- alternating hyperphoria (378.45);
- acquired paralytic strabismus (378.5x);
- paralytic strabismus (378.50);
- ocular motor nerve palsy (378.51-378.52);
- fourth or trochlear nerve palsy (378.53);
- sixth or abducens nerve palsy (378.54);
- external ophthalmoplegia (378.55);
- total ophthalmoplegia (378.56);
- mechanical strabismus (378.60, 378.62);

- brown's sheath syndrome (378.61);
- limited function associated with other conditions (378.63);
- Duane's syndrome (378.71);
- progressive external ophthalmoplegia (378.72);
- strabismus in other neuromuscular disorders (378.73);
- conjugate gaze (378.1, 378.2);
- convergence of insufficiency or palsy (378.83);
- convergence excess or spasm (378.84);
- anomalies of divergence (378.85);
- internuclear ophthalmoplegia (378.86); and
- other dissociation deviation of eye movements (378.87).

Respiratory System:

- laryngeal dystonia (478.75);
- laryngeal spasm (478.75); and
- spastic dysphonia (478.79).

Digestive System:

- anismus (constipation) (564.0);
- esophageal calais (530.0);
- anal stricture (569.2) (751.2-congenital);
- anal spasm (564.6) and anal fissure (565.0); and
- achalasia (530.) 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.

Skin/Subcutaneous Ill Defined:

- primary focal hyperhidrosis (705.21) (see MVP/Preferred Care Hyperhidrosis policy).

Musculoskeletal System and Connective Tissue:

- torticollis (723.5); and
- spasm of muscle (728.85).

Signs/Symptoms Ill Defined:

- hyperhidrosis (780.8) (see MVP/Preferred Care Hyperhidrosis policy)
BTX-B is approved for cervical dystonia (333.83).
Botulinum toxin treatment *is usually allowed **only in the office setting***.
Documentation of the condition must be submitted, indicating the diagnosis, and functional impairment.

- coverage will be limited to four (4) treatments (injections) per year. May include multiple sites per injection per treatment.
**Requests for treatment in an outpatient setting require documentation supporting the medical necessity.*

Special consideration may be given for use of BTX-A for migraine headaches.

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; or
- submitted medical information documents failed standard medical treatments.

There will be no retroactive approvals.

Exclusions/Limitations

- Congenital strabismus (378.9) no coverage.
- Facial wrinkles, frown lines (701.8) no coverage.
- Botulinum Toxin Type A and B Injections are not covered for conditions other than those listed in the Indications/Criteria section of the policy.
- 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 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.
- 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).
- 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 dyssynergia (urinary sphincter spasm with bladder contractions following spinal cord injury);
 - stuttering and vocal tremor;
 - management of tics;
 - headaches other than refractory migraine headaches;
 - myofascial pain;
 - Parkinson's disease;
 - low back pain;
 - neck pain not related to above noted indications; and
 - tremors.
- 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, for the same muscle group, are not covered.

CMS Variation

Botulinum toxin is not covered for the following conditions:

- migraine headaches;
- irritable colon; and
- biliary dyskinesia.

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

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Note: For Preferred Care authorization requirements refer to Appendix A and Appendix B in the Referral/Precertification/Prior Justification/Notification Administrative policy. You may also refer to the "Prior Justification/Precertification of Certain Prescription Drugs" for information on drugs that require precertification and prior justification. Both policies are available on *easyLink* for Providers at www.preferredcare.org.