

Medical Policy



An Independent Licensee of the
Blue Cross and Blue Shield Association.

Title: Botulinum Toxin (BT) (i.e. Botox®, Myobloc®)

Professional

Original Effective Date: February 1996
 Revision Date(s): May, 12, 1998;
 June 1, 1999; January 1, 2001;
 February 1, 2001; July 20, 2004;
 December 29, 2004; October 5, 2005;
 November 3, 2005; December 15, 2005;
 March 10, 2006; May 31, 2006;
 July 18, 2006; October 1, 2006;
 October 19, 2007
 Current Effective Date: July 18, 2008

Institutional

Original Effective Date: June 3, 2004
 Revision Date(s): July 20, 2004;
 December 29, 2004; October 5, 2005;
 November 3, 2005; December 15, 2005;
 March 10, 2006; May 31, 2006;
 July 18, 2006; October 1, 2006;
 October 19, 2007
 Current Effective Date: July 18, 2008

DESCRIPTION

Botulinum toxin (BT) blocks neuromuscular transmission of motor nerves resulting in reduction of muscle activity.

POLICY

Medically Necessary:

- A. The use of botulinum toxin is considered medically necessary in the treatment of the following FDA-approved indications:
 1. Blepharospasm
 2. Cervical dystonia
 3. Facial Nerve VII disorders (hemifacial spasm)
 4. Strabismus
 5. Hyperhidrosis when severe and refractory to first line treatment

- B. The off-labeled use of botulinum toxin is considered medically necessary in the treatment of the following disorders if associated with spasticity:
 1. Equinus foot, if related to spasticity
 2. Hereditary Spastic Paraplegia
 3. Cerebral Palsy (spastic)
 4. Multiple Sclerosis
 5. Neuromyelitis Optica
 6. Schilder's Disease
 7. Spastic Hemiplegia
 8. Spasticity related to stroke, or spinal cord injury
 9. Spasmodic Torticollis

- C. The off-labeled use of botulinum toxin is considered medically necessary in the treatment of the following dystonic disorders:
1. Idiopathic torsion dystonia
 2. Organic writer's cramp
 3. Orofacial dyskinesia (i.e. jaw closure dystonia)
 4. Spasmodic dysphonia or laryngeal dystonia (a disorder of speech due to abnormal control of the laryngeal muscles present only during the specific task of speaking)
 5. Symptomatic torsion dystonia
- D. The off-labeled use of botulinum toxin is considered medically necessary in the treatment of chronic anal fissures.
- E. The off-labeled use of botulinum toxin is considered medically necessary in the treatment of achalasia.
- F. The off-labeled use of botulinum toxin is considered medically necessary in the treatment of incontinence related to detrusor overactivity due to neurogenic causes (i.e. spinal cord injury), when anticholinergic therapy has failed.
- G. Botulinum toxin is considered cosmetic as a treatment of skin wrinkles or other cosmetic indications.
- H. Botulinum toxin is considered investigational in all other cases, including, but not limited to, the following indications:
1. Anismus
 2. Chronic motor tic disorder
 3. Migraine, cluster or other headaches
 4. Fibromyalgia/fibromyositis
 5. Gastroparesis
 6. Myofascial pain syndrome
 7. Back and neck pain not related to conditions mentioned above
 8. Parkinson's disease
 9. Tics associated with Tourette syndrome
 10. Tourette's Syndrome
 11. Tremors
 12. Urinary and anal sphincter dysfunction
 13. Overactive bladder, except as specified above.

DOCUMENTATION

Guidelines for Botulinum toxin use for Spasticity:

1. There must be documented central mediated neurological based spasticity
2. There must be a stated goal of treatment
3. History and physical examination

4. Statement of medical necessity

UTILIZATION

1. Repeat injection would be approved only if improvement was documented from first injection. If no improvement, the injection should NOT be repeated.
2. If it is felt that perhaps a therapeutic level was not obtained initially a booster may be given.
3. Improvement should be noted within four to seven days.
4. Administration -- one to three vials may be used in one treatment. This is dependent on how many muscles are to be injected and the size of the muscles. Any claim using more than three vials or injecting more than three limbs at one time should be reviewed. More muscles than that can be injected at one time, but it needs to be investigated before approving.
5. There is no age limit. It has been found that pre-school children do require a lesser dose. School age children; however, often take an adult dose. This would be clinical judgment.
6. If there is DOCUMENTED IMPROVEMENT with initial treatment then Botulinum toxin may be given every three months. It may be given sooner with individual consideration.
7. May give indefinitely when there is improvement.

CODINGREVENUE CODE

0636

CPT/HCPCS

46505	Chemodenervation of internal anal sphincter
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm or hemifacial spasm)
64613	Chemodenervation of muscle(s); cervical spinal muscle(s) (e.g. spasmodic torticollis)
64614	Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (e.g., for dystonia, cerebral palsy, multiple sclerosis)
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (eg. Scalp, face, neck), per day
67345	Chemodenervation of extraocular muscle
J0585	Botulinum toxin type A (Botox®), per unit
J0587	Botulinum toxin type B (Myobloc®), per 100 units

DIAGNOSIS**These diagnoses are otherwise subject to medical policy as stated above**

333.6	Idiopathic torsion dystonia
333.7	Symptomatic torsion dystonia
333.81	Blepharospasm
333.82	Orofacial dyskinesia
333.83	Spasmodic Torticollis
333.84	Organic writer's cramp
333.89	Other torsion dystonia
334.1	Hereditary spastic paraplegia
340	Multiple Sclerosis
341.0	Neuromyelitis optica
341.1	Schilder's disease
342.10	Spastic hemiplegia, affecting unspecified side
342.11	Spastic hemiplegia, affecting dominant side
342.12	Spastic hemiplegia, affecting nondominant side
343.0	Infantile cerebral palsy, diplegic
343.1	Infantile cerebral palsy, hemiplegic
343.2	Infantile cerebral palsy, quadriplegic
343.3	Infantile cerebral palsy, monoplegic
343.4	Infantile cerebral palsy, infantile hemiplegia
343.8	Infantile cerebral palsy, other specified infantile cerebral palsy
343.9	Infantile cerebral palsy, unspecified
351.0	Facial nerve disorders, Bells palsy
351.1	Facial nerve disorders, Geniculate ganglionitis
351.8	Facial nerve disorders, other facial nerve disorders
351.9	Facial nerve disorders, other
378.00 - 378.9	Strabismus
435.9	Unspecified transient cerebral ischemia
478.75	Laryngeal spasm
478.79	Other diseases of the larynx (spastic dysphonia)
530.0	Achalasia and cardiospasm
565.0	Anal fissure
705.21	Primary focal hyperhidrosis
723.5	Torticollis, unspecified
754.51	Talipes equinovarus
784.49	Spasmodic dysphonia

REVISIONS

07-20-2004	Added "(Note: Botulinum toxin type B for ICD-9 code 333.83 only)" to Policy #1. Added "(Note: for ICD-9 code 333.83 only)", to CPT/HCPCS, J0587.
12-29-2004	Guide for "Botulinum Toxin (BT), Type A for Treatment of Achalasia" and "Botulinum Toxin (BT) Type A and Botulinum Toxin (BT) Type B for Treatment of Spasticity" and merged into one guide and replaced with "Botulinum Toxin".

10-05-2005	In Policy section, off label use, #3, word "Infantile" removed and "(spastic)" added.
11-03-2005	In Policy section added 'Overactive bladder' to the investigational list.
12-15-2005	Added CPT codes: 46505, 64650, 64653.
03-10-2006 effective 05-01-2006	<p>In Policy section deleted "The off-labeled use of botulinum toxin is considered medically necessary for any of the following headache conditions when the criteria for treatment below are met:</p> <ol style="list-style-type: none"> 1. Intractable migraine headaches (with or without aura) at least twice per month causing disability lasting three or more days. 2. Chronic daily headaches defined as patients experiencing more than 15 days of headache per month causing disability lasting three or more days. <p><u>Criteria for Treatment of Headaches:</u> Criteria 1, 2 and 3 below must be met:</p> <ol style="list-style-type: none"> 1. Failed trials of at least three preventive pharmacologic migraine therapies (e.g. beta-blockers, calcium channel blockers, anticonvulsants, antidepressants) with or without concomitant behavioral and physical therapies, after titration to maximal tolerated doses (Note: When patients have contraindications to a treatment it is considered a treatment failure) 2. One of the following abortive medications (e.g. ergotamine, sumatriptan [Imitrex], and zolmitriptan [Zomig]): <ul style="list-style-type: none"> • Required more than twice per week • Contraindicated due to co-existing medical conditions • Failed trials after titration to maximal tolerated doses <p>The frequent use of acute medications (e.g. ergotamine [not DHE], opiates, triptans, simple OTC analgesics, and mixed analgesics containing butalbital, caffeine, or isometheptene) has been ruled out as potential source of rebound headache."</p>
	In Coding title, added "NOTE: Use of any diagnosis code does not guarantee reimbursement. Medical necessity will be based on documentation in the clinical record."
	In References, Government Agency; Medical Society; and Other Authoritative Publications added new #2 BCBSA TEC Assessment 2004.
05-31-2006 effective 07-01-2006	In Policy section, paragraph starting with "Botulinum toxin is considered investigational" #3, added the words Migraine or other so it reads "Migraine, cluster or other headaches". This is for clarification.
	In Coding title deleted "NOTE: Use of any diagnosis code does not guarantee reimbursement. Medical necessity will be based on documentation in the clinical record."
07-18-2006 effective 10-01-2006	In Title section added Myobloc ®.
	In Coding, CPT/HCPCS section, added (Botox®) to J0585 and (Myobloc®) to J0587.
	Deleted ICD-9 Code: 346.9 – Migraine, unspecified.
10-19-2007	In Policy section: <ul style="list-style-type: none"> ▪ B.1 replaced "Cerebral Palsy" with "spasticity".

07-18-2008	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Added "F. The off-labeled use of botulinum toxin is considered medically necessary in the treatment of incontinence related to detrusor overactivity due to neurogenic causes (i.e. spinal cord injury), when anticholinergic therapy has failed." as an indication." ▪ Specified H.13. Overactive bladder by adding "except as specified above."
------------	--

REFERENCES

1. Binder WJ, Brin MF, Blitzer A, et al. Botulinum toxin type A (Botox) for treatment of migraine headaches: An open label study. *Otolaryngology Head Neck Surg.* 2000; 123(6):669-676.
2. Brisinda G, Maria G, Bentivoglio AR. A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure. *NEJM.* 1999; 341:65-69.
3. Davies J, Duffy D, Boyt N, et al. Botulinum toxin (Botox®) reduces pain after hemorrhoidectomy. *Dis Colon Rectum.* 2003; 46:1097-1102.
4. Dodick, DW. Botulinum neurotoxin for the treatment of migraine and other primary headache disorders: from bench to bedside. *Headache.* 2003; 43(Suppl 1):25-33.
5. FriedenberG F, Gollamudi S, Parkman HP. The use of botulinum toxin for the treatment of gastrointestinal motility disorders. *Digestive Diseases and Sciences.* 2004; 49:165-175.
6. Foster L, Clapp L, Erickson M, Jabbari B. Botulinum toxin A and chronic low back pain: A randomized, double-blind study. *Neurology.* 2001; 56(10):1290-3.
7. Freund BJ, Schwartz M. Treatment of chronic cervical-associated headache with botulinum toxin A: A pilot study. *Headache.* 2000; 20:231-236.
8. Koman LA, Paterson Smith B, Balkrishnan R. Spasticity associated with cerebral palsy in children: guidelines for the use of botulinum A toxin. *Pediatric Drugs.* 2003; 5(1):11-23.
9. Koman, LA, Brashear A, Rosenfeld S, et al. Botulinum toxin A neuromuscular blockade in the treatment of equinus foot deformity in cerebral Palsy: A multicenter, open label clinical trial. *Pediatrics.* 2001; 108(5): 1062-71.
10. Lang AM. Botulinum toxin therapy for myofascial pain disorders. *Cur Pain Headache Reports.* 2002; 6.
11. Maria G, Casetta E, Gui D. A comparison of botulinum toxin and saline for the treatment of chronic anal fissure. *NEJM.* 1998; 338: 217-20.
12. Metaxitis D, Seibel A, Doederlein L. Repeated botulinum toxin A injections in the treatment of spastic equinus foot. *Clin Orthop Rel Res.* 2002; 394:177-185.
13. Ondo WG, Hunter C, Moore W, et al. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. *Neurology.* 2004; 62:37-40.
14. Ondo WG, Vuong KD, Derman HS. Botulinum toxin A for chronic daily headache: a randomized, placebo-controlled, parallel design study. *Cephalalgia.* 2004; 24:60-65.
15. Porta M. QA comparative trial of botulinum toxin A ad methylprednisolone for the treatment of myofascial pain syndrome and pain from chronic muscle spasm. *Pain.* 2000; 85:101-105.
16. Rollnik JD, Tanneberger O, Schubert M, et al. Treatment of tension-type headache with botulinum toxin type A: a double-blind, placebo-controlled study. *Headache.* 2000; 40(4):300-5.
17. Relja M, Telarovic S. Botulinum toxin in tension-type headache. *J Neurol.* 2004; 251(Suppl 1):V12-V14.

18. Schmitt WJ, Slowey E, Fravi N, et al. Effect of botulinum toxin A injections in the treatment of chronic tension-type headache: a double blind, placebo-controlled trial. *Headache*. 2001; 41:658-664.
19. Blue Cross and Blue Shield of Kansas Urology Liaison Committee, August 2007.
20. Blue Cross and Blue Shield of Kansas Medical Advisory Committee, November 2007.

Government Agency; Medical Society; and Other Authoritative Publications

1. Blue Cross Blue Shield Assoc. Botulinum toxin for treatment of primary chronic headache disorders. Technology Evaluation Center. 2002. 17(16).
2. Blue Cross Blue Shield Assoc. Botulinum toxin for treatment of primary chronic headache disorders. Technology Evaluation Center. 2004.
3. Hayes Medical Technology Directory. Botulinum toxin treatment for headache. Winifred S. Hayes, Inc., Lansdale PA. November, 2003.
4. Hayes Medical Technology Directory. Botulinum toxin for the treatment of gastrointestinal disorders. Winifred S. Hayes, Inc., Lansdale PA. December, 2003.
5. Hayes Medical Technology Directory. Botulinum toxin treatment for movement disorders. Winifred S. Hayes, Inc., Lansdale PA. March, 2002.
6. Hayes Medical Technology Directory. Local Injection Therapy and Neurosurgery for Cervicogenic Headache and Occipital Neuralgia. Winifred S. Hayes, Inc., Lansdale PA. July, 2003
7. Madoff RD, Fleshman JW. AGA technical review on the diagnosis and care of patients with anal fissure. *Gastroenterology*. 2003; 124(1):235-45.
8. Stephen D. Silberstein. Practice parameter: Evidence-based guidelines for migraine headache - an evidence-based review - Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2000; 55:754-762.
9. Blue Cross and Blue Shield of Kansas Urology Liaison Committee meeting, August 24, 2005 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC-03-05).
10. Blue Cross and Blue Shield of Kansas Medical Advisory Committee meeting, November 3, 2005 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC-03-05).

Web site for Additional Information

1. Dystonia Medical Research Foundation. <http://www.dystonia-foundation.org>. Accessed on September 9, 2004.
2. MyHealth@anthem.com. Health Topics: A-Z. Achalasia. <http://home.anthemhealth.com/topic/topic100586383>. Accessed on September 9, 2004.
3. Institute of Neurological Disorders and Stroke. Cerebral Palsy Information Page.