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Developed By: Medical Criteria Committee	

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Description:

Botulinum toxin is injected intramuscularly at therapeutic doses to produce localized chemical denervation muscle paralysis by blocking peripheral neuromuscular transmission. There are two preparations of botulinum toxin produced by two different strains of bacteria: type A (Botox) and type B (Myobloc). The injections should be given under electromyographic guidance and under the direct supervision of a physician to assure safe and proper administration.

Although botulinum toxin was first FDA approved for use in treatment of strabismus and blepharospasm associated with dystonia, it has been found to be useful in reducing abnormal muscle tone or spasms of arms, hands or feet, and for a variety of other “like” conditions for patients over the age of 12 years. It is not approved for pregnant patients.

Criteria:

ODS will provide coverage for botulinum toxin injections (HCPCS Codes: J0585 and J0587) based on any plan specific limitations for the following conditions:

FDA-Labeled Indications

1. Blepharospasms
2. Facial Nerve Disorders
3. Strabismus
4. Cervical Dystonia

Off-Label FDA Indications

1. Idiopathic torsion dystonia
2. Symptomatic torsion dystonia
3. Orofacial dyskinesia
4. Spasmodic torticollis
5. Organic writer’s cramp
6. Hereditary spastic paraplegia
7. Neuromyelitis Optica
8. Schilder’s disease
9. Spasticity related to stroke, spinal cord injuries, traumatic brain injury, or to demyelinating conditions such as multiple sclerosis
10. Spastic hemiplegia
11. Cerebral palsy
12. Laryngeal spasms or Paralysis of Vocal Cords
13. Esophageal achalasia where the patient has not responded to dilation therapy or where the patient is considered a poor surgical candidate
14. Treatment of chronic anal fissure
15. Central demyelinating disease of CNS
16. Hyperhidrosis – Must meet ODS criteria (see Hyperhidrosis criteria)
17. Disabling essential tremor

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Limited Benefit for Headaches

ODS will provide coverage for the use of botulinum toxin for treatment of headaches. Coverage will be limited to two (2) injections, three months apart for chronic migraine cephalgia, chronic tension-type cephalgia, and chronic cephalgia when **all** of the following have been met:

Negative evaluation for other treatable causes of chronic cephalgia; and

1. Headache frequency >4 episodes a month; and
2. When all other treatment modalities have been exhausted

*Additional injections may be approved for the treatment of headaches if objective measures support a clinical benefit from Botox treatment.

Limited Benefit for Gastroparesis:

ODS will provide coverage for pyloric injection of botulinum toxin for the treatment of gastroparesis when all of the following have been met:

1. Patient has tried and failed dietary modifications; and
2. Patient has documented weight loss; and
3. Patient has significantly delayed gastric emptying as documented by gastric emptying scan of solid food; and
4. Patient is refractory or intolerant to prokinetics and antiemetic medications

When Botulinum toxin injection is not covered

1. For conditions other than those listed above
2. Treatment of wrinkles or other cosmetic indications
3. Botulinum toxin is considered investigational for other indications, including but not limited to myofascial pain syndrome, tremors such as benign essential tremor, chronic motor tic disorder, tics associated with Tourette syndrome, low back pain and piriformis syndrome.

Information to be Submitted with Pre-Authorization Request:

Medical Intake can authorize botulinum toxin injections for all FDA-labeled and off-labeled FDA indications. All other requests must be submitted in writing with the ordering physician's chart records for review for medical necessity. Include diagnostic test results and treatments tried and failed if appropriate.

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- Physician's Advisors