BOTULINUM TOXIN (BOTOX) INJECTION CRITERIA

Description:

Botulinum is a family of toxins produced by the anaerobic organism clostridia botulinum, a bacterial toxin that can paralyze and result in death if consumed in contaminated food. Used as a medicine, purified Botulinum Toxin (BTX) can be used to reduce spasticity or excessive muscular contractions, to relieve pain, to reduce severe spasm and to treat voiding dysfunction severely affecting quality of life (QOL).

Policy/Criteria:

Botulinum toxin (Type A and Type B) intramuscular injections may be considered as chemodenervation treatment for certain medically necessary conditions, such as various muscle spastic disorders and excessive muscle contractions. As of August 2011, the FDA has approved it for use as treatment for voiding dysfunction associated with neurogenic detrusor (bladder) over activity in spinal cord injury or multiple sclerosis. Injections are placed in the bladder muscle wall via cystoscopy. Prior to consideration for authorization, the member must meet all of the following conditions:

1. FDA approved diagnosis
2. Documented failure to conservative therapy for a minimum of 12 consecutive months, such as:
   - At least 3 different anti-spasmolytic agents, anticholinergics, oral, injectable, and/or implementation devices (medications must be titrated to the maximum allowable safe dose without adverse side effects)
   - Physical and occupational therapy (as applicable to diagnosis)
   - Other established methods used to control and/or treat spastic conditions
3. Treatment is included as part of an integrated antispasticity program
4. Treatment is not used to treat widespread, severe spasticity
5. Spasticity prevents function or independence, such as body positioning, mobility, and/or basic hygiene
6. Spasticity causes chronic pain unrelieved by pain medication and/or therapy in a structured pain management program.
7. Treatment is for overactive bladder in spinal cord injury and/or multiple sclerosis after failed treatment with anticholinergics i.e. ditropan, oxybutinin, or alpha 1antagonist- Terazone or failed bladder training.

Non-Coverage

Botulinum toxin will not be considered for authorization for any of the following:

1. Investigational and/or not medically necessary conditions, including but not limited to:
   - Cosmetic, including skin wrinkles
   - Headache (Except migraine’s which may be considered on a case by case basis)
   - Carpal tunnel syndrome
   - Low back pain
   - Drooling, stuttering
   - Tics, whether or not associated with Tourette Syndrome
   - Anismus
   - Fibromyalgia/fibromyositis
   - Parkinson’s disease
   - Sweaty palms and feet (hyperhidrosis)

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1 Aetna Clinical Policy Bulletin 0113 May 2012
2. Treatment of smooth muscle spasm
3. Patient and/or caregiver demonstrate evidence of noncompliance in prescribed treatment plan(s).
4. Development of antibodies to BTX
5. Treatment will likely not positively affect quality of life
6. Patient is not taking aminoglycoside antibiotics
7. Failed satisfactory clinical response with initial trial of botulinum injections

**For patient safety, we do not cover** botulinum (Botox™) injections for:
- Patients who are pregnant or intend to become pregnant
- Patients who are on aminoglycoside therapy, as it may increase the risk of problems between the muscles and the nerves
- Patients with retrobulbar hemorrhages sufficient to compromise retinal circulation
- Patients with severe laryngeal or respiratory weakness
- Patients with sensitivity or allergy to Botox, or known high antibody titers to Botox.²

**Documentation Requirements:**

The treating physician must provide documentation to establish an approved diagnosis, the intractability to medical treatment, and all other conditions outlined in the Policy/Criteria and Contraindications section of this policy. Clinical documentation must be submitted with the request for prior authorization and must include:

- Detailed history and physical, including family history
- Antibody testing and other pertinent laboratory results
- Ancillary study results to confirm diagnosis, such as but not limited to: EMG, CT scans, MRA/MRI, etc.
- Neurological evaluation, including passive and active range of motion, muscular activity, functional disability and ADL assessment
- Description of symptoms, i.e., hypertonicity, clonus, scissors gait, etc.
- Physician progress notes
- Prior treatment, including type of treatment, length of treatment trial and patient response
- Pain assessment (if present and related to spasms)
- Treatment for spasm-related pain and patient response
- Treatment for overactive bladder and patient response in spinal cord injury and/or multiple sclerosis

**Prior Authorization Guidelines:**

Chemodenervation with BTX requires prior authorization by THC. The final decision rests with the Medical Director. Approval will be based on eligibility, documentation demonstrating medical necessity, the potential for notable improvement in spasticity, or bladder control and the potential for significant improvement in quality of life. Medical documentation must demonstrate sustained clinical improvement is the expected outcome with elimination of reoccurrence. THC reserves the right to refer the member for an independent second medical opinion to assist in the decision-making process.

**Billing Guidelines:**

Botulinum toxin Type A is supplied in vials, each vial contains 100 units. At present, Type A (Botox) is only available in a 100-unit size. Reimbursement will be for the number of units administered to the authorized member.

Botulinum toxin Type B (Myobloc) is supplied in amounts of 2,500U, 5,000U, and 10,000U. Reimbursement will be for the number of units administered.
Once reconstituted, both Type A and Type B have a shelf life of 4 hours. To ensure quality health care, physicians are encouraged to schedule patients in such a way they can use Botulinum toxin most efficiently, if an authorized THC member receives less than the supplied dose. When a vial is not split between patients, reimbursement will reimburse the unused portion of the drug. The medical record must contain documentation of the exact dosage of the drug given and the exact amount of the discarded portion.

Reimbursement will allow for one injection per each functional muscle group or anatomical area regardless of the number of injections made into each group or the number of muscles that compose it.

Authorization will be for no more than two (2) consecutive treatments, the second treatment to be given a minimum of 90 days after the initial dose. In the case of voiding dysfunction, 6-9 months after first injection treatment.

**Continued Treatments:**

Consideration for continued treatment after the initial treatment period requires re-application for prior authorization. The treating physician must provide compelling clinical evidence of medical necessity, along with a written request, for continued chemodenervation with botulinum toxin. Documentation must also include the clinical effectiveness of the injections. Treatment continued for duration beyond 12 months also requires lab testing for antibody resistance.

Members must obtain a referral if the primary care physician does not provide services.

Services must be provided in an affiliated facility.

**The Medical Director must authorize all requests for consideration.**

2 Blue Cross Blue Shield of Massachusetts, Medical Policy, Policy #:006, Botulinum Toxin,