

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** Botulinum Toxin Treatment Policy

**Drug(s):** BOTOX (clostridium botulinum toxin type A), MYOBLOC (clostridium botulinum toxin type B)

**Covered Uses:**

All FDA-approved indications not otherwise excluded from Part D.

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

1) Neuromuscular

- Extrapyrimalidal 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)
- spasm of muscles

2) Ophthalmologic

- Blepharospasm
- enophthalmos
- 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
- laryngeal spasm

4) Gastrointestinal

- Achalasia as alternative treatment for members who meet one of the following criteria:
  - have multiple medical problems or elderly greater than 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
- anal stricture

5) Dermatologic

- Axillary hyperhidrosis: severe disabling focal axillary hyperhidrosis refractory to topical treatment and/or other conservative treatment as approved by the FDA.

6) Urologic

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

All criteria in "other criteria" section must be met for coverage.

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.

**Required Medical Information:** Medical history. Documentation of the condition must be submitted, indicating the diagnosis, functional impairment, and previous treatment and responses

**Age Restrictions:** For CP: restricted to greater than 18 months and less than 8 years old. All other indications restricted to 12 years old and above.

**Prescriber Restrictions:** N/A

**Other Criteria:** Failure of standard therapy. FOR: achalasia: as alternative treatment for members who meet one of the following criteria:

- have multiple medical problems or elderly greater than 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.
- 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.

**Exclusion Criteria:**

- Botulinum Toxin Type A and B Injections are not covered for conditions other than those listed in the "Covered Uses" section.
- 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.

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- 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.
- Botulinum Toxin Type A and B injections, for the treatment of cerebral palsy, are not indicated for members:
  - who are beginning treatment at less than 18 months of age or greater than 8 years of age, information and review by the Medical Director),
  - with severe fixed contractures or
  - with diffuse hypertonia. Botulinum
- 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.
- Toxin Type A and B injections, given at intervals less than 3 months, for the same muscle group, are not covered.

**Coverage Duration:** initial 3 month approval with extensions up to one year