AETNA BETTER HEALTH®
Prior Authorization guideline for Botulinum Toxins

Drugs Covered
- Botox
- Dysport
- Myobloc
- Xeomin

Authorization guidelines

For patients who meet the following:
- Medically accepted use (Not covered when used for cosmetic purposes)
- Prescribed by an appropriate specialist based on indication
- Additional criteria based on diagnosis:
  - Chronic Limb Spasticity due to hereditary spastic paraplegia, spastic hemiplegia due to stroke, traumatic brain or spinal cord injury, or MS or other demyelinating diseases of the CNS:
    - Trial and failure of baclofen and at least one other formulary muscle relaxant such as tizanidine or dantrolene
    - Trial and failure or concurrent utilization of physical and/or occupational therapy
    - Abnormal muscle tone is either interfering with functional ability, OR is expected to result in joint contracture
    - Age restriction: restricted to FDA or compendia accepted age ranges for product
  - Severe primary axillary hyperhidrosis
    - Medical complications from hyperhidrosis are present such as skin maceration with secondary skin infections
    - Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS)
    - Trial and failure of a 2 month trial of topical aluminum chloride 20%
    - Age restriction: must be at least 18 years old
  - Migraine Prophylaxis
    - Documented frequency of more than 15 migraine headaches in a 30-day period with each headache lasting 4 hours or longer and
    - Member had inadequate response to or intolerable side effects with at least 3 medications from TWO classes of migraine headache prophylaxis medication for at least 2 months (60days):

Last Review: 10/2017
Previous PARP Approval: 12/2016
Current PARP Approval: 11/2017
- Beta-blocker: propranolol, metoprolol, timolol, atenolol, nadolol
  - Anticonvulsant: valproic acid or divalproex, topiramate
  - Antidepressants: amitriptyline, venlafaxine
    - Age restriction: must be at least 18 years old

- Neurogenic bladder
  - Trial and failure of 2 formulary first-line agents, such as oxybutynin, tolterodine and trospium
  - Failure of behavioral therapy (i.e., bladder training or pelvic floor exercises)
    - Age restriction: must be at least 18 years old

- Overactive bladder:
  - Failure of behavioral therapy (i.e., bladder training or pelvic floor exercises)
  - Trial and failure of 3 formulary urinary anticholinergics (i.e., oxybutynin, trospium, tolterodine).
    - Age restriction: must be at least 18 years old

- Sialorrhea (excessive drooling) associated with neurological disorders (i.e., Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy)
  - Trial and failure of glycopyrrolate and benztropine
  - Patient has medically significant complications (i.e., chronic skin maceration or uncontrolled infections)
    - Age restriction: must be at least 3 years old

- Off-label use† for Achalasia:
  - Request is for Botox
  - Patient meets ONE of the following:
    - Patient remains symptomatic despite surgical myotomy or pneumatic dilation
    - Patient is not a candidate for surgical myotomy or pneumatic dilation or refuses procedure(s)
    - Patient presents with atypical achalasia symptoms and Botox is needed to help guide therapy and/or confirm diagnosis
    - Malignancy at esophagogastric junction has been ruled out by endoscopic evaluation
    - Age restriction: must be at least 18 years old

- Off-label use† for chronic anal fissures:
  - Request is for Botox
  - Trial and failure of nitroglycerin ointment 0.4% (Rectiv) for at least 3 weeks AND either bulk fiber supplements, stool softeners, or sitz baths for at least 1 month
    - Age restriction: must be at least 18 years old

- Off-label use† for spasticity or equinus gait due to Cerebral palsy:
  - Request is for Botox or Dysport
  - Patient is ambulatory and has participated in or is currently being managed with occupational therapy
    - Age restriction: pediatric patient (2-18 years of age)
Botulinum toxins may also be reviewed for medical necessity for treatment of the following indications:

- *Botox* for *cervical dystonia* in patients at least 16 years old
- *Dysport, Myobloc, Xeomin* for *cervical dystonia* in patients at least 18 years old
- *Botox* for *blepharospasm* in patients at least 12 years old
- *Xeomin* for *blepharospasm* in patients at least 18 years old who were previously treated with onabotulinumtoxinA (Botox)
- *Botox* for *strabismus* in patients at least 12 years old and with deviations of <50 prism diopters
- *Botox* for off-label use† for *hemifacial spasm* in patients at least 18 years old

Note: Additional information may be required on a case-by-case basis to allow for adequate review

†Off-label indications included based on peer-reviewed clinical studies

**Additional Information:**

Botulinum Toxins are NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

**Approval Duration:**

Initial Approval:
1 treatment/12 weeks x 6 mo

Renewal:
1 treatment/12 weeks x 1 yr

*Botox:* Should not exceed a cumulative dose of 400 units every 90 days

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.
Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References: