I. Medication Description

Botulinum toxin is produced from fermentation of different strains of Clostridia Botulinum bacteria. These toxins act as potent neurotoxins by preventing the release of acetylcholine at the neuromuscular junction resulting in paralysis of muscle fibers at the site of injection. Botulinum toxins have been approved by the FDA for the treatment of several otherwise difficult to treat conditions, typically related to muscle/nerve spasticity.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Botulinum toxin will be covered for the following conditions (in addition to medication-specific FDA-approved indications):

- Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) – for this use:
  - The member must be at least 16 years old \textbf{AND}
  - The condition must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck \textbf{AND}
  - The member must have a history of recurrent involuntary contraction of one or more of the muscles of the neck (e.g. sternocleidomastoid, splenius, trapezius, or posterior cervical muscles)
  - Required documentation: progress notes, history and physical exam including description of abnormal posturing, head position, symptoms related to diagnosis.

- Hyperhidrosis: Primary focal (axillary, palmar, craniofacial) or gustatory (Frey’s Syndrome) when the following criteria are met:
  - Documented failure of first line therapy (i.e. topical medications, when appropriate) in an adult member \textbf{AND}
  - One of the following:
    - The condition is causing repeated skin infection or episodes of skin breakdown \textbf{OR}
    - The condition is significantly impacting activities of daily living, such as ability to perform functions of work or school
  - Required documentation: progress notes, history and physical including member self-assessment where disability measures are used for medical necessity.
• Dystonia/spasticity resulting in functional impairment (interference with joint junction, mobility, communication, nutritional intake) or pain in members with any of the following diagnoses:
  o Focal dystonias
    ▪ Blepharospasm associated with dystonia in patients 12 years of age or older
    ▪ Focal upper limb dystonia (e.g. organic writer’s cramp)
    ▪ Orofacial/oromandibular dystonia (Orofacial dyskinesias, Meige syndrome)
    ▪ Laryngeal dystonia (aductor spasmodic dysphonia)
    ▪ Idiopathic (primary or genetic) torsion dystonia
    ▪ Symptomatic (acquired) torsion dystonia
  o Spastic conditions:
    ▪ Cerebral palsy
    ▪ Spasticity related to stroke
    ▪ Acquired spinal cord or brain injury
    ▪ Spastic quadriplegia/paresis
    ▪ Spastic hemiplegia/paresis
    ▪ Spastic paraplegia/paresis
    ▪ Neuromyelitis optica (NMO, or Devic’s Disease)
    ▪ Multiple sclerosis or Schilder’s disease
• Sialorrhea associated with Parkinson’s disease, cerebral palsy, amyotrophic lateral sclerosis, or other neurological disorders
• Strabismus in patients 12 years of age or older
• Bladder dysfunction in adults who have an inadequate response to or are intolerant of an anticholinergic medication with one of the following diagnoses:
  o Urinary incontinence due to detrusor over activity, either idiopathic or due to neurogenic causes (e.g. spinal cord injury, multiple sclerosis.)
  o Overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency.
• Prophylaxis of headaches in adult members with chronic migraine (defined as at least 15 days per month with headache lasting at least 4 hours per day):
  o Diagnosis has been made by a prescribing or referring neurologist AND
  o At least ONE of the following is true:
    ▪ Member has been unable to tolerate or has had an inadequate response to minimum of TWO 6-week trials with different types of specific prophylactic medications with sufficient evidence to support use in migraines (for example: antiepileptics, antidepressants, antihypertensives) OR
    ▪ Member has been unable to tolerate or has had inadequate response to minimum of three monthly injections (3 months) OR two quarterly injections (6 months) of a calcitonin gene-related peptide (CGRP) receptor inhibitor therapy for the treatment of chronic migraine AND
  o Member is not concurrently receiving a CGRP receptor inhibitor for the treatment of migraines AND
  o Required documentation has been provided: Initial request should include current progress notes or consultation report from specialist, detailing: diagnosis, treatment history, headache frequency (incidence, days per month), reported severity (e.g. pain scale). Member self-
assessment questionnaire or headache diary should be included if available.

- Piriformis syndrome where at least three of the following treatment modalities have been tried:
  - Anesthetic injections – beneficial, however short-lasting relief
  - Anti-inflammatory/acetaminophen/opioid therapy- insufficient efficacy
  - Physical therapy- insufficient efficacy
  - Steroid injections- insufficient efficacy
  - Chiropractic care/osteopathic manipulative treatment- insufficient efficacy

IV. Quantity Limitations

Coverage is provided for an adequate quantity to treat the specific condition. The dosing and treatment schedule of Botulinum toxin will vary depending on condition being treated and medication being used. Members receiving treatments from more than one practitioner or for more than one condition will be covered at a total cumulative maximum dosage within recommendations for the given medication(s).

V. Coverage Duration

Coverage is available for a maximum of 12 month intervals, though shorter durations of time may be applied when initial testing for response is taking place.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following:

- Stabilization of disease, improvement in disease symptoms, or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug AND
- Dosage administered and frequency of administration is supported by FDA-approved dosing guidelines or other accepted published clinical support AND

Required Documentation at Renewal:

- Chronic Migraine: comparative migraine frequency at time of renewal compared to pre-treatment (either by: progress notes, member questionnaire, migraine diary or consult report).
- Hyperhidrosis: progress notes or member self-assessment noting specifics of response to treatment (e.g. decrease in infection or skin irritation, or member self-assessment of impact of botulinum toxin treatment of ability to perform ADLs)
- Other diagnoses: current progress notes or consultation report with specifics of symptom improvement attributed to botulinum toxin treatments.

VII. Billing/Coding Information

- Botox
  - J0585
  - 1 billable unit = 1 unit of Botox
- Dysport
  - J0586
  - 1 billable unit = 5 units of Dysport
• Myobloc
  o J0587
  o 1 billable unit = 100 units of Myobloc

• Xeomin
  o J0588
  o 1 billable unit = 1 unit of Xeomin

VIII. Summary of Policy Changes

  • 1/1/12:
    o Changed wording from “chronic daily headache” to wording as found in the Botox Prescribing
      Information/Indication.
    o Included specific examples of first-line therapies for hyperhidrosis
    o Coverage for the treatment of plantar hyperhidrosis considered investigational and not covered
    o Coverage for sialorrhea available when associated with neurological disorders
    o Policy exclusion list limited
    o Maximum coverage duration is expanded to 12 month intervals

  • 12/15/12:
    o Specific / required documentation added to cervical dystonia, chronic migraine, hyperhidrosis and
      renewal portions of policy.
    o Required prior trials of migraine prophylaxis medications changed to two.
    o Added: maximum dosing limitations for members receiving treatments of multiple conditions.
    o Addition of age requirement for migraine prophylaxis
    o Addition of pregnancy information

  • 2/2013: updated policy to reflect new FDA-approval for the treatment of overactive bladder with symptoms
    of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or are
    intolerant of an anticholinergic medication.

  • 12/15/13: removal of repetitive listings between sections II and III.

  • 9/15/14: No policy changes

  • 7/1/15: formulary distinctions made

  • 9/15/15: criteria updated for craniofacial hyperhidrosis

  • 10/1/15: ICD9 references omitted

  • 8/8/16: added age requirement for treatment of cervical dystonia

  • 3/3/17: removed anticholinergic requirement for treatment of hyperhidrosis

  • 5/1/17: step therapy criteria added and piriformis syndrome criteria updated

  • 6/21/17: no policy changes

  • 1/1/18: updated coverage criteria; requests for all diagnostic codes will require prior authorization;
    addendum with diagnostic codes exceptions removed

  • 6/15/18: no policy changes

  • 11/1/18: updated criteria addressing concurrent use with CGRP receptor inhibitors for the treatment of
    migraines and removed step therapy verbiage

  • 8/15/19: no policy changes

  • 1/30/20: updated criteria regarding requested trials of medications for the treatment of chronic migraines
IX. References


147. Aimovig™ [prescribing information]. Thousand Oaks, California: Amgen Inc.; May 2018


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.