

Policy: MBP 11.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Botulinum Toxin and Derivatives (Botox, Dysport, Myobloc, Xeomin)

I. Policy:

Botulinum Toxin A (Botox)
(Dysport)
(Xeomin)
Botulinum Toxin B (Myobloc)

II. Purpose/Objective:

To provide a policy of coverage regarding Botulinum Toxin and Derivatives

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. 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.

DESCRIPTION:

Botulinum Toxin injections are used to treat various focal muscle spastic disorders. They produce presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical denervation of muscle produces local paralysis and allows individual muscles to be weakened selectively.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Botulinum Toxin Type A (Botox and Xeomin) are considered to be medically necessary for the commercial, exchange, and CHIP lines of business for following indications when the following criteria are met (Note: The Medicare line of business is reviewed according to Centers for Medicare and Medicaid Services [CMS] Local Coverage Determination [LCD]):

Medical record documentation of a diagnosis of:

1. **Strabismus in members \geq 12 years of age**
2. **Blepharospasm associated with dystonia in members \geq 12 years of age**
3. **Facial nerve (VII) disorders**
4. **Cervical dystonia**
5. **Chronic Migraine Headache**

Botulinum toxin A for the treatment of chronic migraine headache may be considered medically necessary when all of the following criteria are met:

- Physician provided medical record documentation of a history of 15 or more migraine headache days per month that last 4 or more hours per day **AND**
- Physician provided medical record documentation that Botox is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Physician provided medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/sodium valproate
 - Amitriptyline
 - Venlafaxine

AND

- Medical record documentation that Botox will not be used in combination with a CGRP antagonist **OR**
- If the request is for use in combination with a CGRP antagonist, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

6. Primary Axillary Hyperhidrosis

Botulinum toxin A for the treatment of severe primary axillary, palmar or pedal hyperhidrosis may be considered medically necessary when the following criteria are met:

- Physician provided documentation of failure of a 6 month trial of non-surgical treatments with topical dermatologics (e.g., aluminum chloride, tannic acid, lutealdehyde, anticholinergics) **AND**
- Medical record documentation of one of the following:
 - Underlying chronic medical condition such as dermatitis, fungal condition, skin maceration, or secondary microbial condition as a result of hyperhidrosis **OR**
 - Sweating is intolerable and causes functional impairment that interferes with member's ability to perform age-appropriate professional or social normal daily activities

7. Urinary incontinence due to neurogenic bladder

Botulinum toxin A for the treatment of urinary incontinence due to neurogenic bladder is considered medically necessary when the following criteria are met:

- Medical record documented failure of anticholinergic medication therapy

8. Overactive Bladder

Botulinum toxin A for the treatment of overactive bladder is considered medically necessary when the following criteria are met:

- Medical record documentation of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults **AND**
- Medical record documentation of failure of two anticholinergic medication therapies **AND**
- Medical record documentation of a minimum of three urinary urgency incontinence episodes and at least 24 micturations in three days

9. Torsion dystonia
10. Orofacial dyskinesia
11. Spasmodic torticollis
12. Organic writer's cramp
13. Hereditary spastic paraplegia
14. Multiple sclerosis
15. Neuromyelitis optica
16. Schilder's disease
17. Spastic hemiplegia
18. Infantile cerebral palsy
19. Esotropia
20. Exotropia
21. Intermittent heterotropia
22. Other and unspecified heterotropia
23. Heterophoria
24. Paralytic strabismus
25. Mechanical strabismus
26. Unspecified disorder of eye movements
27. Laryngeal spasm
28. Achalasia and cardiospasm
29. Anal spasm
30. Anal fissure
31. **Upper Limb Spasticity**

Botulinum toxin A for the treatment of upper limb spasticity is considered medically necessary when the following criteria are met:

- Patient is at least 2 years of age **AND**
- Medical record documentation that Botox or Xeomin is being used for the treatment of upper limb spasticity

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Botox** only) are:

1. **Lower Limb Spasticity**

- Medical record documentation that Botox is being used for the treatment of lower limb spasticity to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus) **AND**
- Documentation that patient is at least 2 years of age **AND**
- Medical record documentation of failure to control spasticity with conventional therapies, e.g., physical therapy, splinting/bracing, or systemic antispasticity medication

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Dysport**) are:

1. **Cervical dystonia**

OR

2. **Upper Limb Spasticity**

- Medical record documentation that Dysport is being used for the treatment of upper limb **AND**
- Documentation that the patient is ≥ 2 years of age.

OR

3. **Lower Limb Spasticity**

- Medical record documentation that Dysport is being used for the treatment of the lower limb(s) **AND**
- Documentation that the member is ≥ 2 years of age.

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Xeomin** only) are:

1. Sialorrhea

- Documentation that patient is at least 2 years of age **AND**
- For adults ages 18 years or older: Medical record documentation of a diagnosis of chronic sialorrhea resulting from Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury **OR**
- For pediatric patients ages 2 to 17 years: Medical record documentation of a diagnosis of chronic sialorrhea resulting from cerebral palsy, other genetic or congenital disorders, or traumatic brain injury

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type B (**Myobloc**):

1. Cervical dystonia in adults
2. Chronic Sialorrhea in adults

The following applies to all botulinum toxin products (Botox, Dysport, Myobloc, Xeomin):

Quantity Limit: One (1) visit per 12 weeks (3 months)*

**Note: Patients utilizing botulinum toxin products for more than one indication may require additional visits. The following cumulative doses should not be exceeded if being used for 1 (or more) indication(s):*

- *Botox – 400 units per 12 weeks (3 months)*
- *Dysport – 1500 units per 12 weeks (3 months)*
- *Myobloc – 5000 units per 12 weeks (3 months)*
- *Xeomin – 400 units per 12 weeks (3 months)*

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Medical record documentation of continued disease improvement or lack of disease progression** **AND**
- Medical record documentation of one of the following:
 - Repeated administrations are not being given more frequently than once every 12 weeks **OR**
 - Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing more frequently than every 12 weeks.

AND

- For Chronic Migraines:
 - Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
 - Medical record documentation that Botox will not be used in combination with a CGRP antagonist **OR**
 - If the request is for use in combination with a CGRP antagonist, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

***Note: The requested medication will no longer be covered if the patient fails to present clinical benefit after two sequential therapies using maximum doses.*

Botulinum toxin is considered **investigational** for

- headache or migraine other than chronic migraine
- myofascial pain syndrome
- tremors such as benign essential tremor, chronic motor tic disorder, and tics associated with Tourette syndrome

As treatment of wrinkles or other cosmetic indications. Cosmetic procedures are an exclusion per the "Exclusions" section of the applicable benefit documents

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/00

Revised: 12/00; 01/01; 02/01; 03/01; 08/01; 09/01;10/01; 05/02; 05/03 (Coding, definition); 04/05 (exclusion clarification), 03/06 (update references); 1/07 (add indication); 4/09 (ref.) 1/10 (add Dysport); 12/10 (add indication); 1/13 (indication and criteria); 8/13 (added indication), 09/15/15 (added indication), 11/17/15(added upper limb spasticity for Dysport), 5/17/16 (added upper limb spasticity for Xeomin and lower limb spasticity for Botox), 11/15/16 (Dysport pediatric lower limb), 11/21/17(dysport, LLS, auth duration, QL), 11/20/18 (Xeomin for sialorrhea), 3/19/19 (CGRP's), 11/19/19 (spasticity age), 1/21/20 (age and indication), 3/17/20 (Botox chronic migraine update, Dysport pediatric upper limb spasticity), 1/19/21 (Xeomin age), 12/15/22 (Migraine formulary alternatives, Medicaid Business Segment, LOB carve out)

Reviewed: 04/02; 02/08; 2/14; 1/20/15 (Medicaid Business Segment, formatting, added to criteria and investigation use, updated references), 10/31/17, 9/28/18, 1/13/22