Geisinger

POLICIES AND PROCEDURE MANUAL

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, **onabotulinumtoxinA (Botox)** is 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 that the proposed injection sites and dosage regimen are consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature for the requested indication **AND**

- Medical record documentation of a diagnosis of:
  1. **Strabismus in members ≥ 12 years of age**
  2. **Blepharospasm associated with dystonia in members ≥ 12 years of age**
  3. **Facial nerve (VII) disorders (Hemifacial spasm)**
  4. **Cervical dystonia (Spasmodic torticollis)**
  5. **Chronic Migraine Headache**
     - 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**
     - Physician provided documentation of failure of a 6 month trial of non-surgical treatments with topical dermatologics (e.g., aluminum chloride, tannic acid, luteraldehyde, antichloinergics) **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**
     - Medical record documented failure of anticholinergic medication therapy
  8. **Overactive Bladder**
     - 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. **Oromandibular dystonia**
  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. **Chronic Anal fissure**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line therapy (can include but is not limited to fiber, sitz bath, topical analgesic, or topical vasodilators [nifedipine or nitroglycerin])
31. **Chronic Sialorrhea in members ≥18 years of age**
    - Medical record documentation of chronic sialorrhea caused by a neurological disease (eg. Parkinson's Disease, Cerebral Palsy, Amyotrophic Lateral Sclerosis [ALS]) **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line therapy (can include but is not limited to glycopyrrolate, hyoscyamine, amitriptyline, or atropine)
32. **Upper and/or Lower Limb Spasticity in members ≥2 years of age**
    - Medical record documentation of <u>one</u> of the following:
    - The spasticity is associated with a condition causing limb spasticity (can include but is not limited to cerebral palsy [including spastic equinus foot deformities], multiple sclerosis, neuromyelitis optica, or other injury, disease or tumor of the brain or spinal cord) **OR**
    - The spasticity interferes with activities of daily living

    AND
    - Medical record documentation of <u>one</u> of the following:
        - Therapeutic failure on, intolerance to, or contraindication to an oral medication for spasticity (can include but is not limited to baclofen, tizanidine, diazepam, or dantrolene) **OR**
        - The oral medications for spasticity are not expected to adequately treat the condition

Botulinum Toxin Type A, **AbobotulinumtoxinA** (**Dysport**), is 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 that the proposed injection sites and dosage regimen are consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature for the requested indication **AND**

- Medical record documentation of a diagnosis of:
  1. **Cervical dystonia (Spasmodic torticollis)**
  2. **Upper or Lower Spasticity in members ≥2 years of age**
     - Medical record documentation of <u>one</u> of the following:
     - The spasticity is associated with a condition causing limb spasticity (can include but is not limited to cerebral palsy [including spastic equinus foot deformities], multiple sclerosis, neuromyelitis optica, or other injury, disease or tumor of the brain or spinal cord) **OR**
     - The spasticity interferes with activities of daily living

       AND
     - Medical record documentation of <u>one</u> of the following:
     - Therapeutic failure on, intolerance to, or contraindication to an oral medication for spasticity (can include but is not limited to baclofen, tizanidine, diazepam, or dantrolene) **OR**
     - The oral medications for spasticity are not expected to adequately treat the condition
  3. **Chronic anal fissure**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line therapy (can include but is not limited to fiber, sitz bath, topical analgesic, or topical vasodilators [nifedipine or nitroglycerin])

4. **Primary Axillary Hyperhidrosis**
   - Physician provided documentation of failure of a 6 month trial of non-surgical treatments with topical dermatologics (e.g., aluminum chloride, tannic acid, luteraldehyde, antichloinergics) **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
5. **Chronic Sialorrhea**
   - Medical record documentation of chronic sialorrhea caused by a neurological disease (eg. Parkinson's Disease, Cerebral Palsy, Amyotrophic Lateral Sclerosis [ALS]) **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line therapy (can include but is not limited to glycopyrrolate, hyoscyamine, amitriptyline, or atropine)
6. **Blepharospasm**
7. **Facial nerve (VII) disorders (Hemifacial spasm)**
8. **Orofacial dyskinesia**
9. **Oromandibular dystonia**

Botulinum Toxin Type A, **IncobotulinumtoxinA** (**Xeomin**), is 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 that the proposed injection sites and dosage regimen are consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature for the requested indication **AND**

- Medical record documentation of a diagnosis of:
  1. **Chronic Sialorrhea in patients 2 years of age and older**
     - Medical record documentation of chronic sialorrhea caused by a neurological disease (eg. Parkinson's Disease, Cerebral Palsy, Amyotrophic Lateral Sclerosis [ALS]) **AND**
     - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line therapy (can include but is not limited to glycopyrrolate, hyoscyamine, amitriptyline, or atropine)
  2. **Blepharospasm**
  3. **Cervical Dystonia (Spasmodic torticollis)**
  4. **Upper Limb Spasticity**
     - Medical record documentation of <u>one</u> of the following:
       - If the patient is $\geq$ 18 years of age: The spasticity is associated with a condition causing limb spasticity (can include but is not limited to cerebral palsy [including spastic equinus foot deformities], multiple sclerosis, neuromyelitis optica, or other injury, disease or tumor of the brain or spinal cord) OR the spasticity interferes with activities of daily living **OR**
       - If the patient is 2 to 17 years of age (inclusive): The spasticity is NOT caused by cerebral palsy

     AND
     - Medical record documentation of <u>one</u> of the following:
       - Therapeutic failure on, intolerance to, or contraindication to an oral medication for spasticity (can include but is not limited to baclofen, tizanidine, diazepam, or dantrolene) **OR**
       - The oral medications for spasticity are not expected to adequately treat the condition

Botulinum Toxin Type B, **RimabotulinumtoxinB** (**Myobloc**), is 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 that the proposed injection sites and dosage regimen are consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature for the requested indication **AND**

- Medical record documentation of a diagnosis of:
  1. **Cervical dystonia (Spasmodic torticollis)**
  2. **Chronic Sialorrhea in patients ≥18 years of age**
     - Medical record documentation of chronic sialorrhea caused by a neurological disease (eg. Parkinson's Disease, Cerebral Palsy, Amyotrophic Lateral Sclerosis [ALS]) **AND**
     - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line therapy (can include but is not limited to glycopyrrolate, hyoscyamine, amitriptyline, or atropine)
  3. **Upper Limb Spasticity**
     - Medical record documentation of <u>one</u> of the following:
       - The spasticity is associated with a condition causing limb spasticity (can include but is not limited to cerebral palsy [including spastic equinus foot deformities], multiple sclerosis, neuromyelitis optica, or other injury, disease or tumor of the brain or spinal cord) **OR**
       - The spasticity interferes with activities of daily living
     - **AND**
       - Medical record documentation of <u>one</u> of the following:
         - Therapeutic failure on, intolerance to, or contraindication to an oral medication for spasticity (can include but is not limited to baclofen, tizanidine, diazepam, or dantrolene) **OR**
         - The oral medications for spasticity are not expected to adequately treat the condition

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 – 1,500 units per 12 weeks (3 months)*
- *Myobloc – 10,000 units per 12 weeks (3 months)*
- *Xeomin – 400 units per 12 weeks (3 months)*

AUTHORIZATION DURATION: Initial approval will be for **12 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 **unproven** (data is inconclusive) for:

- Temporomandibular joint disorders (TMJ or TMD) and/or Myofascial pain of the muscles of mastication

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
- Trigeminal neuralgia
- Gastroparesis

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 spasticiy 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), 11/7/23 (July P&T criteria changes, formatting)

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