RX.PA.005.MPC BOTOX, DYSPORT, MYOBLOC, XEOMIN

The purpose of this policy is to define the prior authorization process for Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), Mybloc® (rimabotulinumtoxinB), and Xeomin® (incobotulinumtoxinA).

Botox® (onabotulinumtoxinA) is indicated for:

- Treatment of strabismus in patients ≥12 years of age
- Treatment of blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients ≥12 years of age
- Treatment of cervical dystonia, spasticity in the flexor muscles of the elbow, wrist, and fingers in adult patients, to reduce the severity of abnormal head position and neck pain
- Treatment of severe, primary axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- Prophylaxis of headaches in adult patients with chronic migraine (>15 days per month with headache lasting 4 hours a day or longer)
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of upper and lower limb spasticity in adult patients
- Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age
- Treatment of lower limb spasticity in pediatric patients 2 to 17 years of age

Dysport® (abobotulinumtoxinA), is indicated for:

- The treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients
- Spasticity in adults
- Treatment of lower limb spasticity in pediatric patients 2 years of age and older
- The treatment of upper limb spasticity in pediatric patients 2 years of age and older

Mybloc® (rimabotulinumtoxinB) is indicated for the treatment of adults with:

- cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

- chronic sialorrhea

Xeomin® (incobotulinumtoxinA) is indicated for the treatment of:

- Cervical dystonia in adults
- Chronic sialorrhea in patients 2 years and older
- Upper limb spasticity in patients age 2 years and older, excluding spasticity caused by cerebral palsy
- Blepharospasm in adults previously treated with Botox® (onabotulinumtoxinA)

Although similar in certain aspects, it is important to understand that Botox®, Dysport®, Mybloc®, and Xeomin® are unique products that are not interchangeable. The units of biological activity of one botulinum toxin product cannot be compared to or converted into units of any other botulinum toxin product.

FDA has determined that post-marketing safety data from approved botulinum toxins suggest that botulinum toxin effects may, in some cases, be observed beyond the site of local injection. Based upon this new safety information, FDA has required that the manufacturers of botulinum toxin products add a boxed warning regarding the distant spread of toxin effect to the package insert.

PROCEDURE

A. <u>Initial Authorization Criteria:</u>
Must meet all of the criteria listed under the respective diagnosis:

1. Botox® (onabotulinumtoxinA):
   - Must have a diagnosis of:
     - Strabismus
       - Must be 12 years of age and older
       - Must be prescribed by an ophthalmologist
     - Blepharospasm associated with dystonia including benign essential blepharospasm or VII nerve disorders
       - Must be 12 years of age and older
       - Must be prescribed by an ophthalmologist
     - Cervical dystonia (spasmodic torticollis)
       - Must be 16 years of age and older
       - Documented abnormal head position or abnormal posturing with limited range of motion in the neck
       - Documentation of recurrent involuntary muscle contractions in the neck
       - Documentation that no prior surgical intervention has occurred
       - Documentation that other neuromuscular disorders have been ruled out
       - Must be prescribed by a neurologist, or physical medicine and rehabilitation physician
     - Spasticity in the flexor muscles of the elbow, wrist or fingers in adults

- Spasticity in the upper limb(s) in patients 2 years of age and older
- Spasticity in the lower limb in:
  - Adults
  - Pediatric patients 2 to 17 years of age
  - Must be prescribed by a neurologist , or physical medicine and rehabilitation physician.
- Severe primary axillary hyperhidrosis that is inadequately managed by topical agents
  - Must be prescribed by a dermatologist
  - Must be 18 years of age or older
  - Must have a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4
  - Must have tried 10-20% topical aluminum chloride for at least 3 months with an inadequate response or adverse effect of a severe rash
- Chronic migraine (to be used for prophylaxis of headaches in adult patients)
  - Must be prescribed by a neurologist
  - Must be 18 years of age or older
  - Must have all of the following:
    - Headache occurring on 15 or more days per month for at least 3 consecutive months
    - 8 or more of the total headache days each month being migraine or probable migraine days
    - Having >4 distinct headache episodes each lasting >4 hours a day or longer
  - Must not be using opioids >10 days per month
  - Must have documentation of an adequate trial (of at least 2 months each) of 2 prophylactic therapy classes to include beta-blockers with an inadequate response
    - Additional prophylactic therapy classes to consider are calcium channel blockers or angiotensin converting enzyme inhibitors (ACEIs).
  - Must not be used in conjunction with a CGRP antagonist (e.g. Rimegepant, Ubrogepant, Eptinezumab, etc.)
- Urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who meet the following criteria:
  - Must have a previous trial and failure of an anticholinergic medication
  - Must be prescribed by a urologist or a fellowship-trained urogynecologist
- Overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who meet the following criteria:
  - Must be prescribed by a urologist or a fellowship-trained urogynecologist
  - Must have > 3 urinary urgency incontinence episodes in a 3-day period
  - Must have > 8 micturitions per day
  - Must provide chart documentation showing specific examples of how quality of life is impacted by disease (e.g. sleep disturbances, work disruption, decrease in social interactions, etc.)
  - Must have a trial and failure of behavioral therapy (includes but not limited to weight loss, dietary changes, exercise, etc.)

        - Must have an adequate trial (of at least 4 weeks) at the recommended dose of 2 anticholinergic medications with an inadequate response or intolerance

2. Dysport® (abobotulinumtoxinA):
    - Must have a diagnosis of:
        - Cervical dystonia (spasmodic torticollis)
            - Must be 18 years of age and older
            - Documented abnormal head position or abnormal posturing with limited range of motion in the neck
            - Documentation of recurrent involuntary muscle contractions in the neck
            - Documentation that no prior surgical intervention has occurred
            - Documentation that other neuromuscular disorders have been ruled out
            - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician.
        - Spasticity in adults
        - Spasticity in the lower limb(s) in children 2 years of age and older
        - Spasticity in the upper limb(s) in children 2 years of age and older
            - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician.
3. Myobloc® (rimabotulinumtoxinB):
    - Must have a diagnosis of:
        - Cervical dystonia (spasmodic torticollis)
            - Must be 18 years of age and older
            - Documented abnormal head position or abnormal posturing with limited range of motion in the neck
            - Documentation of recurrent involuntary muscle contractions in the neck
            - Documentation that no prior surgical intervention has occurred
            - Documentation that other neuromuscular disorders have been ruled out
            - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician.
        - Chronic sialorrhea
            - Must be 18 years of age and older
            - Must be prescribed by a neurologist or otolaryngologist

4. Xeomin® (incobotulinumtoxinA):
    - Must have a diagnosis of one of the following:
        - Cervical dystonia (spasmodic torticollis)
            - Must be 18 years of age and older
            - Documented abnormal head position or abnormal posturing with limited range of motion in the neck
            - Documentation of recurrent involuntary muscle contractions in the neck
            - Documentation that no prior surgical intervention has occurred
            - Documentation that other neuromuscular disorders have been ruled out
            - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician.

- Blepharospasm in adults
  - Must have previously been treated with Botox
  - Must be prescribed by an ophthalmologist
- Spasticity in the upper limb(s) in patients 2 years and older, excluding spasticity caused by cerebral palsy
  - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician.
- Chronic sialorrhea in patients 2 years of age and older
  - Must be prescribed by a neurologist or otolaryngologist

Maryland Physicians Care also acknowledges the following diagnoses for consideration of coverage per the American Academy of Neurology Therapeutics and Technology Assessment Subcommittee evidence based review, category Level A (established as effective for the given condition in the specified population in at least two consistent class I studies) or Level B (probably effective for the given condition in the specified population in at least one class I study or at least two class II studies) evidence showing efficacy:

5. Autonomic Disorders
   - Axillary hyperhidrosis subject to previously noted criteria
   - Neurogenic detrusor overactivity in adults after trial and failure of at least one previous agent
   - Detrusor sphincter dyssynergia after spinal cord injury
   - Drooling in Parkinson's Disease
   - Must be prescribed by a neurologist or dermatologist

6. Spasticity
   - Spasticity in adults due to stroke, trauma, multiple sclerosis, and neoplasm involving the CNS.
   - Spasticity due to cerebral palsy, brain injury, spinal cord injury, stroke, multiple sclerosis, or encephalopathy in children.
   - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician.

7. Movement Disorders
   - Blepharospasm
   - Cervical dystonia
   - Focal upper extremity dystonia
   - Adductor laryngeal dystonia
   - Essential hand tremor in patients after trial and failure of at least one previous agent
   - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician.

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Botox, Dysport, Myobloc, Xeomin will be considered investigational or experimental for any other use and coverage may be provided if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, DrugDex, Lexi-Drug, etc…) or at least two published peer-reviewed randomized controlled trials for the treatment of the diagnosis(es) for which it is prescribed. Abstracts (including meeting abstracts) are excluded from review consideration. These requests will be reviewed on a case by case basis to determine medical necessity.

D. <u>Reauthorization Criteria:</u>
All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6 month to 12 month intervals based upon the indication of use and all of the following:

- MPC Renewal:
  - Documentation from the provider that the member remains a candidate for treatment with Botox/Dysport/Xeomin/Myobloc based upon the prescriber's assessment while on therapy
  - Documentation that the member's motor function and/or strength has stabilized or improved as compared to baseline
  - Must be prescribed by a neurologist for treatment of chronic migraines, autonomic disorders, movement disorders
  - Must not be used in conjunction with a CGRP antagonist (e.g. Rimegepant, Ubrogepant, Eptinezumab, etc.) for the treatment of chronic migraines
  - Must be prescribed by a neurologist, or a physical medicine and rehabilitation physician for treatment of cervical dystonia and spasticity disorders
  - Must be prescribed by a neurologist or otolaryngologist for chronic sialorrhea
  - Must be prescribed by an ophthalmologist for treatment of strabismus, blepharospasm
  - Must be prescribed by a dermatologist for treatment of primary axillary hyperhidrosis
  - Must be prescribed by a urologist or a fellowship trained urogynecologist for treatment of urinary incontinence, overactive bladder
  -
- Renewal from Previous Insurer:
  - Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
  - Provider has documented positive clinical response to therapy for the member from baseline

LIMITATIONS

Length of Authorization (if above criteria met)	
Initial Authorization	1 course of treatment (3 months)
Reauthorization	OAB: 6 months All other conditions: 1 year
Quantity Limits	
Botox®	• 100 U vial: 4 vials per 84 days • 200 U vial: 2 vials per 84 days
Dysport®	• 2 vials per 84 days
Myobloc®	• 2,500 U vial: 4 vials per 84 days • 5,000 U vial: 2 vials per 84 days • 10,000 U vial: 1 vial per 84 days
Xeomin®	• 50 U vial: 8 vials per 84 days • 100 U vial: 4 vials per 84 days • 200 U vial: 2 vials per 84 days

CODES: J Code(s)

CODE	DESCRIPTION
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Selection Revision *Chronic migraines: removal of adequate trial requirements of TCAs, Anticonvulsants, SSRIs, SNRIs*	*06/2026*
Annual review	*02/2026*
Annual review	*02/2025*
Annual review *Change in Non-MPC renewal to renewal from previous insurer*	*02/2024*
Selected Revision Reauthorization: Addition of prescribing requirement by a neurologist, or a physical medicine and rehabilitation physician for treatment of cervical dystonia and spasticity disorders Addition to initial and reauthorization sections: Must not be used in conjunction with a CGRP antagonist (e.g. Rimegepant, Ubrogepant, Eptinezumab, etc.)	*01/2024*
Selected Revision *Requirement of specialists prescribing per indication*	*10/2023*
Annual review	*02/2023*
Update to reauthorization section to include MPC vs Non-MPC criteria. Expanded criteria requirements and updated FDA approved age groups for the following indications: cervical dystonia, primary axillary hyperhidrosis, chronic sialorrhea and blepharospasm	*09/2022*

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Update to off-label restrictions	*04/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*