Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **OnabotulinumtoxinA (Botox), abobotulinumtoxinA (DysportTM), rimabotulinumtoxinB (Myobloc), and incobotulinumtoxinA (Xeomin)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***May 2003 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: September 2018

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

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

Botox 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 patietns, 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 limb spasticity in adult patients

Dysport 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

Myobloc 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.

Xeomin is indicated for the treatment of adults with:
- Cervical dystonia
- Chronic sialorrhea
- Upper limb spasticity
- Blepharospasm in adults previously treated with onabotulinumtoxinA

Although similar in certain aspects, it is important to understand that Botox, Dysport, Myobloc, 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 and implement a Risk Evaluation and Mitigation Strategy (REMs), including the requirement for the distribution of a Medication Guide each time a patient is injected with a botulinum toxin product.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to

make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, onabotulinumtoxinA (Botox), abobotulinumtoxinA (DysportTM), rimabotulinumtoxinB (Myobloc), and incobotulinumtoxinA (Xeomin), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Myobloc and Xeomin are subject to the preferred medical drug list program. This program applies to the botulinum toxins products specified in this policy. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a non-preferred product. Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Botulinum Toxins

	Product(s)
Preferred	• Botox **(onabotulinumtoxinA)** • Dysport **(abobotulinumtoxinA)**
Non-preferred	• Myobloc **(rimabotulinumtoxinB)** • Xeomin **(incobotulinumtoxinA)**

Requests for a non-preferred drug must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION CRITERIA (*Use for Myobloc/Xeomin Requests Only*)

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

A. Member is currently receiving treatment with the non-preferred product through health insurance, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
B. Member has had a documented inadequate response or intolerable adverse event to BOTH preferred products.
C. Member is requesting Xeomin for the treatment of blepharospasm and has had a documented inadequate response or an intolerable adverse event to Botox.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed under the respective drug product:

1. OnabotulinumtoxinA (Botox):

- Must have a diagnosis of:
  - Strabismus
  - Blepharospasm associated with dystonia including benign essential blepharospasm or VII nerve disorders in patients greater than 12 years old
  - Cervical dystonia (spasmodic torticollis)
  - Spasticity in the flexor muscles of the elbow, wrist or fingers in adults
  - Spasticity in the upper limb(s) in adults
  - Severe primary axillary hyperhidrosis that is inadequately managed by topical agents
    - Must be prescribed by a dermatologist
    - Must have tried 10-20% topical aluminum chloride 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 an adequate trial of at least 2 months each of 3 prophylactic therapy classes to include beta-blockers, anticonvulsants, and tricyclic antidepressants (TCAs) with an inadequate response.
      - For members in whom one of these therapy classes is not clinically appropriate and/or members with significant side effects/intolerance to one of these therapy classes, additional prophylactic therapy classes may be considered. Additional prophylactic therapy classes to consider are calcium channel blockers, selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), or angiotensin converting enzyme inhibitors (ACEIs).
  - 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
  - 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. AbobotulinumtoxinA (Dysport):

- Must have a diagnosis of:
  - Cervical dystonia (spasmodic torticollis) in adults
  - Spasticity in adults
  - Spasticity in the lower limb(s) in children 2 years of age and older

3. RimabotulinumtoxinB (Myobloc):

- Must have a diagnosis of cervical dystonia (spasmodic torticollis)

4. IncobotulinumtoxinA (Xeomin):

- Must be an adult with one of the following:
  - Must have a diagnosis of cervical dystonia (spasmodic torticollis)
  - Must have a diagnosis of blepharospasm and have previously been treated with Botox
  - Spasticity in the upper limb(s)
  - Chronic sialorrhea

The Health Plan 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:

1. **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

2. 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.

3. 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

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy. Additionally the following criteria must be met for the conditions listed below:

- Chronic migraine:
    - Chart documentation from the prescriber indicating that the member's chronic migraines have been reduced in frequency and/or severity as a result of therapy as per patient headache journal.
- Overactive bladder:
    - Chart documentation from the prescriber indicating that the member has at least 2 urinary incontinence episodes in a 3 day period.

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

If the established criteria are not met, the request is referred to a Medical Director for review.

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria Update	*10/16, 08/17, 09/18*
Preferred Product Update (effective 4/1/18)	*02/18*