RX.PA.005.CCH BOTULINUM NEUROTOXINS

The purpose of this policy is to define the prior authorization process for Botox® (onabotulinumtoxinA), Daxxify® (daxibotulinumtoxinA-lanm), Dysport® (abobotulinumtoxinA), Myobloc® (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 patients ≥ 16 years of age, 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
- Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age or older

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

Myobloc® (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 age 2 years and older
- Upper limb spasticity in patients age 2 years and older, excluding spasticity caused by cerebral palsy
- Blepharospasm in adults

Daxxify® (daxibotulinumtoxinA-lanm) is indicated for the treatment of cervical dystonia in adult patients.

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.

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 and approval by the Medical Policy Committee.

The drugs, Botox® (onabotulinumtoxinA), Daxxify® (daxibotulinumtoxinA-lanm), Dysport® (abobotulinumtoxinA), Myobloc® (rimabotulinumtoxinB), and Xeomin® (incobotulinumtoxinA), are subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:

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

1. Botox® (onabotulinumtoxinA):
- Must not be requesting more than 400 units per visit
- 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) in patients 16 years of age and older
- 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 patients 2 years of age and older
- Spasticity in adults due to stroke, trauma, multiple sclerosis, and neoplasm involving the CNS
- Spasticity in children due to cerebral palsy, brain injury, spinal cord injury, stroke, multiple sclerosis, or encephalopathy
- Detrusor sphincter dyssynergia after spinal cord injury
- Drooling in Parkinson's Disease in adults
- Focal upper extremity dystonia
- Adductor laryngeal dystonia
- Essential hand tremor
    - Must be age 18 years or older
    - Must have a trial and failure of at least one previous agent
- Severe primary axillary hyperhidrosis that is inadequately managed by topical agents
    - Must be prescribed by a dermatologist
    - Must be age 18 years or older
    - 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 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 **TWO** 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 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, who meet the following criteria:
  - Must be age 18 years of age or older
  - 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 lifestyle modifications (e.g., pelvic floor muscle exercises, weight loss, dietary changes, smoking cessation, modification of contributory medications/substance)
  - Must have an adequate trial (of at least 4 weeks) at the recommended dose of 2 anticholinergic medications with an inadequate response or intolerance
- Neurogenic detrusor overactivity (NDO)
  - Must be 5 years of age or older
  - For adults, must have a trial and failure of at least one previous agent [e.g., alpha-blockers (prazosin, terazosin), anticholinergics (oxybutynin, tolterodine), bethanechol, ephedrine, tricyclic antidepressants (impramine)]

2. Dysport® (abobotulinumtoxinA):

- Must not be requesting more than 1,000 units per visit
- Must have a diagnosis of:
  - Blepharospasm
  - Cervical dystonia (spasmodic torticollis) in adults
  - 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
  - Spasticity in adults due to stroke, trauma, multiple sclerosis, and neoplasm involving the CNS

- Spasticity in children due to cerebral palsy, brain injury, spinal cord injury, stroke, multiple sclerosis, or encephalopathy
- Axillary hyperhidrosis
  - 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
- Neurogenic detrusor overactivity in adults
  - Must have a trial and failure of at least one previous agent [e.g., alpha-blockers (prazosin, terazosin), anticholinergics (oxybutynin, tolterodine), bethanechol, ephedrine, tricyclic antidepressants (impramine)]
- Detrusor sphincter dyssynergia after spinal cord injury
- Drooling in Parkinson's Disease in adults
- Focal upper extremity dystonia
- Adductor laryngeal dystonia
- Essential hand tremor
  - Must be age 18 years or older
  - Must have a trial and failure of at least one previous agent

3. Myobloc® (rimabotulinumtoxinB):

- Must not be requesting more than 10,000 units per visit
- Must have a diagnosis of:
  - Cervical dystonia (spasmodic torticollis) in patients aged 18 years or older
  - Chronic sialorrhea in patients aged 18 years or older
  - Blepharospasm
  - Spasticity in adults due to stroke, trauma, multiple sclerosis, and neoplasm involving the CNS
  - Spasticity in children due to cerebral palsy, brain injury, spinal cord injury, stroke, multiple sclerosis, or encephalopathy
  - Axillary hyperhidrosis
    - 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
  - Neurogenic detrusor overactivity in adults
    - Must have a trial and failure of at least one previous agent [e.g., alpha-blockers (prazosin, terazosin), anticholinergics (oxybutynin, tolterodine), bethanechol, ephedrine, tricyclic antidepressants (impramine)]
  - Detrusor sphincter dyssynergia after spinal cord injury
  - Drooling in Parkinson's Disease in adults
  - Focal upper extremity dystonia

- Adductor laryngeal dystonia
- Essential hand tremor
    - Must be age 18 years or older
    - Must have a trial and failure of at least one previous agent

4. Xeomin® (incobotulinumtoxinA):

- Must not be requesting more than 400 units per visit
- Must have a diagnosis of one of the following:
    - Cervical dystonia (spasmodic torticollis) in adults
    - Blepharospasm in adults
        - Must have previously been treated with Botox
    - Spasticity in the upper limb(s) in patients aged 2 years and older
    - Chronic sialorrhea in patients aged 2 years and older
    - Spasticity in adults due to stroke, trauma, multiple sclerosis, and neoplasm involving the CNS
    - Spasticity in children due to cerebral palsy, brain injury, spinal cord injury, stroke, multiple sclerosis, or encephalopathy
    - Axillary hyperhidrosis
        - 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
    - Neurogenic detrusor overactivity
        - Must be age 18 years or older
        - Must have a trial and failure of at least one previous agent [e.g., alpha-blockers (prazosin, terazosin), anticholinergics (oxybutynin, tolterodine), bethanechol, ephedrine, tricyclic antidepressants (impramine)]
    - Detrusor sphincter dyssynergia after spinal cord injury
    - Drooling in Parkinson's Disease in adults
    - Focal upper extremity dystonia
    - Adductor laryngeal dystonia
    - Essential hand tremor
        - Must be age 18 years or older
        - Must have a trial and failure of at least one previous agent

5. Daxxify® (daxibotulinumtoxinA-lanm)

- Must not be requesting more than 250 units per visit
- Must have a diagnosis of cervical dystonia in adult patients

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 or stabilized 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 showing that the member currently has at least 2 urinary incontinence episodes in a 3-day period, indicating the member's symptoms have returned

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J0585	BOTOX	INJECTION, ONABOTULINUMTOXINA, 1 UNIT
J0586	DYSPORT	INJECTION, ABOBOTULINUMTOXINA, 5 UNITS
J0587	MYOBLOC	INJECTION, RIMABOTULINUMTOXINB, 100 UNITS
J0588	XEOMIN	INJECTION, INCOBOTULINUMTOXINA, 1 UNIT
J0589	DAXXIFY	INJECTION, DAXIBOTULINUMTOXINA-LAMN, 1 UNIT

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22
Modify prerequisite requirements and approval durations for migraine reviews	7/22
Update approval durations to 1 year	02/23
Added Daxify (Injection, daxibotulinumtoxina-lanm, 1 unit)	08/24

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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