 Neuromuscular Blocking Agents

This Prior Authorization request will be reviewed for medical necessity only. Benefits are subject to the terms and conditions of the patient's contract. Please contact Wellmark customer service at the number on the patient's card with benefit questions.

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Neuromuscular Blocking Agent policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Botox (onabotulinumtoxinA) and Dysport (abobotulinumtoxinA) are the preferred products. The criteria will require the use of the health plan's preferred products before the use of targeted products (Myobloc, Xeomin), unless there are clinical circumstances that exclude the use of the preferred products and may be based on previous use of a product.

Botulinum toxin is a protein produced by the bacterium Clostridium Botulinum. There are seven distinct serotypes designated as type, A, B, C-1, D, E, F and G. Only Type A and Type B preparations are currently available in the United States. When administered intramuscularly, all botulinum toxins reduce muscle tone by interfering with the release of acetylcholine from nerve endings.

U.S. Food and Drug Administration (FDA)-approved labeled indications are few, but botulinum toxin has been used for a wide variety of off-label indications.

Exclusions
Coverage will not be provided for cosmetic use.

Botox (onobotulinum toxin A)
FDA approved indications

- Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of upper limb spasticity in adult patients
- Treatment of lower limb spasticity in adult patients
- Cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
- Severe primary axillary hyperhidrosis that is inadequately managed with topical agents
- Strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above

Compendial Uses

- Achalasia
- Chronic anal fissures
- Essential tremor
- Excessive salivation secondary to advanced Parkinson’s disease
- Hemifacial spasm
- Spasmodic dysphonia (laryngeal dystonia)
- Lower and upper limb spasticity in pediatric patients

**Myobloc (rimabotulinumtoxin B)**

FDA approved indications

- Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia (adult patients)
- Treatment of chronic sialorrhea in adults

**Dysport (abobotulinumtoxin A)**

FDA approved indications

- Treatment of cervical dystonia in adults
- Treatment of spasticity (upper and/or lower limb) in adults
- Treatment of lower limb spasticity in pediatric patients 2 years of age and older

Compendial Uses

- Treatment of benign essential blepharospasm

**Xeomin (incobotulinumtoxin A)**

FDA approved indications

- Cervical dystonia in adult patients
- Blepharospasm in adults
- Upper limb spasticity in adults
- Chronic sialorrhea in adults
Table. Botulinum Toxins

<table>
<thead>
<tr>
<th>Medication</th>
<th>Generic Name</th>
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<tr>
<td><strong>Preferred Products:</strong></td>
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<tr>
<td>Botox</td>
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<td>Dysport</td>
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<td><strong>Targeted Products:</strong></td>
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<td>Myobloc</td>
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**POLICY**

**Criteria for Initial Approval**

**Botox**

A. **Blepharospasm**
   
   Authorization of 24 months may be granted for treatment of blepharospasm.

B. **Cervical dystonia**
   
   Authorization of 24 months may be granted for treatment of cervical dystonia (e.g., torticollis)

C. **Chronic migraine prophylaxis**
   
   Authorization of 6 months (two injection cycles) may be granted for treatment of chronic migraine prophylaxis when all of the following criteria are met:
   1. Member experiences headaches ≥ 15 days per month
   2. Member completed adequate trial (≥ 8 weeks) of an oral migraine preventative therapy such as:
      a. Divalproex sodium (Depakote, Depakote ER)
      b. Topiramate (Topamax)
      c. Gabapentin (Neurontin)
      d. Amitriptyline (Elavil)
      e. Venlafaxine (Effexor)
      f. Atenolol/Metoprolol/Propranolol/Timolol/Nadolol
      g. Nimodipine/Verapamil
      h. Naproxen/other NSAID

D. **Overactive bladder with urinary incontinence**
   
   Authorization of 12 months may be granted for treatment of overactive bladder with urinary incontinence when the patient has had an inadequate response or experienced intolerance to an anticholinergic medication (e.g., Vescicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trosipium], Ditropan XL [oxybutynin]).

E. **Primary axillary hyperhidrosis**
   
   Authorization of 12 months may be granted for treatment of primary axillary hyperhidrosis.

F. **Strabismus**
   
   Authorization of 12 months may be granted for treatment of strabismus.
G. **Upper limb spasticity**  
Authorization of 24 months may be granted for treatment of upper limb spasticity.

H. **Lower limb spasticity**  
Authorization of 24 months may be granted for treatment of lower limb spasticity.

I. **Urinary incontinence associated with a neurologic condition (eg, spinal cord injury, multiple sclerosis)**  
Authorization of 24 months may be granted for treatment of urinary incontinence associated with a neurologic condition (eg, spinal cord injury, multiple sclerosis) when the patient has had an inadequate or experienced intolerance to an anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).

J. **Achalasia**  
Authorization of 24 months may be granted for treatment of achalasia.

K. **Chronic anal fissures**  
Authorization of 12 months may be granted for treatment of chronic anal fissures.

L. **Essential tremor**  
Authorization of 24 months may be granted for treatment of essential tremor.

M. **Excessive salivation due to advanced Parkinson's disease**  
Authorization of 24 months may be granted for treatment of excessive salivation due to advanced Parkinson's disease.

N. **Hemifacial spasm**  
Authorization of 24 months may be granted for treatment of hemifacial spasm.

O. **Spasmodic dysphonia (laryngeal dystonia)**  
Authorization of 24 months may be granted for treatment of spasmodic dysphonia (laryngeal dystonia).

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**Myobloc**

A. **Cervical dystonia**  
Authorization of 24 months may be granted for treatment of cervical dystonia (e.g., torticollis) when ANY of the following criteria is met:
- The patient is currently receiving treatment with Myobloc through health insurance, excluding if obtained as samples or via manufacturer's patient assistance programs.
- The patient has had an inadequate response or an intolerable adverse event to both preferred products, Botox and Dysport.

B. **Chronic sialorrhea**  
- Authorization of 24 months may be granted for treatment of chronic sialorrhea

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**Dysport**

A. **Cervical dystonia**  
Authorization of 24 months may be granted for treatment of cervical dystonia (e.g., torticollis)

B. **Upper limb spasticity**  
Authorization of 24 months may be granted for treatment of upper limb spasticity.
C. **Lower limb spasticity**  
Authorization of 24 months may be granted for treatment of lower limb spasticity (e.g., cerebral palsy, multiple sclerosis).

D. **Blepharospasm**  
Authorization of 24 months may be granted for treatment of blepharospasm.

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**Xeomin**

B. **Cervical dystonia**  
Authorization of 24 months may be granted for treatment of cervical dystonia (e.g., torticollis) when **ANY** of the following criteria is met:
- The patient is currently receiving treatment with Xeomin through health insurance, excluding if obtained as samples or via manufacturer’s patient assistance programs.
- The patient has had an inadequate response or an intolerable adverse event to both preferred products, Botox and Dysport.

C. **Blepharospasm**  
Authorization of 24 months may be granted for treatment of blepharospasm when **ANY** of the following criteria is met:
- The patient is currently receiving treatment with Xeomin through health insurance, excluding if obtained as samples or via manufacturer’s patient assistance programs.
- The patient has had an inadequate response or an intolerable adverse event to Botox.

D. **Upper limb spasticity**  
Authorization of 24 months may be granted for treatment of upper limb spasticity when **ANY** of the following criteria is met:
- The patient is currently receiving treatment with Xeomin through health insurance, excluding if obtained as samples or via manufacturer’s patient assistance programs.
- The patient has had an inadequate response or an intolerable adverse event to both preferred products, Botox and Dysport.

E. **Chronic sialorrhea**
- Authorization of 24 months may be granted for treatment of chronic sialorrhea

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**Continuation of Therapy**

A. All patients (including new patients) requesting authorization for continuation of therapy must meet **ALL** initial authorization criteria for all approvable conditions other than chronic migraine prophylaxis.

B. Authorization of 12 months may be granted for treatment of chronic migraine prophylaxis when the patient has achieved or maintained a 50% reduction in monthly headache frequency since starting therapy with Botox.

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Botox, Dysport, Myobloc, and Xeomin are considered **not medically necessary** for members who do not meet the criteria set forth above.

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**Dosage and Administration**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

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**Quantity Limits**

Botox 400 units per 12 week interval; Myobloc 10,000 per 12 week interval; Dysport 1,000 units per 12 week interval; Xeomin 400 units per 12 week interval
Appendices
Preventative Therapies for Migraine

A. Antiepileptic drugs
   - Divalproex sodium
   - Topiramate
   - Gabapentin

B. Antidepressants
   - Amitriptyline
   - Venlafaxine

C. Beta-blockers
   - Atenolol
   - Metoprolol
   - Propranolol
   - Nadolol
   - Timolol

D. Calcium channel blockers
   - Nimodipine
   - Verapamil

E. Nonsteroidal anti-inflammatory drugs
   - Naproxen

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0585 Injection, onabotulinumtoxinA (Botox), 1 unit
- J0586 Injection, abobotulinumtoxinA (Dysport), 5 units
- J0587 Injection, rimabotulinumtoxinB (Myobloc), 100 units
- J0588 Injection, incobotulinumtoxinA (Xeomin), 1 unit

REFERENCES

## POLICY HISTORY

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<td>May 1991</td>
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<tr>
<td><strong>Reviewed:</strong></td>
<td>July 2019</td>
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<td>July 2019</td>
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