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 over activity 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
- 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, excluding spasticity caused by cerebral palsy
- Cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain
- Severe primary axillary hyperhidrosis that is inadequately managed with topical agents in adult patients
- Strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

Compendial Uses
- Achalasia
- Chronic anal fissures
- Essential tremor
- Excessive salivation
- Hemifacial spasm
- Spasmodic dysphonia (laryngeal dystonia)
- Oromandibular dystonia
- Myofascial pain syndrome
- Focal hand dystonia
- Facial myokymia
- Hirschsprung disease with internal sphincter achalasia
- Orofacial tardive dyskinesia
- Painful bruxism
- Palatal myoclonus
- First bite syndrome
- Palmar or gustatory (Frey’s syndrome) hyperhidrosis
- Lower and upper limb spasticity in pediatric patients
- Myofascial pain syndrome

**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
- Treatment of chronic sialorrhea in adults

Compendial Uses
- Primary axillary and palmar hyperhidrosis
- Upper limb spasticity

**Dysport** (abobotulinumtoxin A)
FDA Approved Indications
- Treatment of cervical dystonia in adults
• Treatment of spasticity (upper and/or lower limb) in adults
• Treatment of upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy
• Treatment of lower limb spasticity in pediatric patients 2 years of age and older

Compendial Uses
• Blepharospasm
• Hemifacial spasm
• Chronic anal fissures
• Excessive salivation
• Primary axillary hyperhidrosis

Xeomin (incobotulinumtoxin A)
FDA Approved Indications
• Treatment of cervical dystonia in adult patients
• Treatment of blepharospasm in adult patients
• Treatment of upper limb spasticity in adult patients
• Treatment of chronic sialorrhea in adult patients

Table. Botulinum Toxins

<table>
<thead>
<tr>
<th>Medication</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td><strong>Preferred Products:</strong></td>
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<tr>
<td>Botox</td>
<td>onabotulinumtoxinA</td>
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<tr>
<td>Dysport</td>
<td>abobotulinumtoxinA</td>
</tr>
<tr>
<td><strong>Targeted Products:</strong></td>
<td></td>
</tr>
<tr>
<td>Myobloc</td>
<td>rimabotulinumtoxinB</td>
</tr>
<tr>
<td>Xeomin</td>
<td>incobotulinumtoxinA</td>
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</tbody>
</table>

POLICY

Criteria for Initial Approval

**Botox**

**A. Blepharospasm**
Authorization of 12 months may be granted for treatment of blepharospasm.

**B. Cervical dystonia**
Authorization of 12 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 with headaches lasting longer than 4 hours
2. Member completed an adequate trial of three oral migraine preventative therapies coming from at least 2 of the following classes with a trial of each medication at least 60 days in duration:
   • Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine)
   • Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium)
   • Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol)
• Calcium channel blockers (e.g., amlodipine, diltiazem, felodipine).

3. Member must not use any CGRP-inhibitors and Botox together

4. Member’s headache has at least two of the following:
   • Aggravated by routine movement
   • Moderate to severe pain intensity
   • Pulsating
   • Unilateral

5. Member’s headache has at least one of the following:
   • Nausea/vomiting
   • Sensitivity to light
   • Sensitivity to sound

D. **Overactive bladder with urinary incontinence**
   Authorization of 12 months may be granted for treatment of overactive bladder with urinary incontinence, urgency, and frequency when all of the following criteria are met:
   1. The member has tried and failed behavioral therapy.
   2. The member has had an inadequate response or experienced intolerance to two anticholinergic medications (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).

E. **Primary axillary, palmer, and gustatory (Frey’s syndrome) hyperhidrosis**
   Authorization of 12 months may be granted for treatment of primary axillary, palmar, or gustatory (Frey’s syndrome) hyperhidrosis when all of the following criteria are met:
   1. Member is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines); and
   2. Significant disruption of professional and/or social life has occurred because of excessive sweating; and
   3. Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

F. **Strabismus**
   Authorization of 12 months may be granted for treatment of strabismus when interference with normal visual system development is likely to occur and spontaneous recovery is unlikely.
   Note: Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion..

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

H. **Lower limb spasticity**
   Authorization of 12 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 12 months may be granted for treatment of urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) when all of the following criteria are met:
   1. The member has tried and failed behavioral therapy
   2. The member has had an inadequate response 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 12 months may be granted for treatment of achalasia when the member has tried and failed conventional therapy such as pneumatic dilation and surgical myotomy.

K. **Chronic anal fissures**
Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first line therapy such as topical calcium channel blockers or topical nitrates.

L. **Essential tremor**
Authorization of 12 months may be granted for treatment of essential tremor.

M. **Excessive salivation**
Authorization of 24 months may be granted for treatment of excessive salivation (chronic sialorrhea) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

N. **Hemifacial Spasm**
Authorization of 12 months may be granted for treatment of hemifacial spasm.

O. **Spasmodic dysphonia (laryngeal dystonia)**
Authorization of 12 months may be granted for treatment of spasmodic dysphonia (laryngeal dystonia).

P. **Oromandibular dystonia**
Authorization of 12 months may be granted for treatment of oromandibular dystonia.

Q. **Myofascial Pain Syndrome**
Authorization of 12 months may be granted for treatment of myofascial pain syndrome when the member has tried and failed all of the following:
1. Physical Therapy
2. Injection of local anesthetics into trigger points
3. Injection of corticosteroids into trigger points

R. **Focal hand dystonia**
Authorization of 12 months may be granted for the treatment of focal hand dystonias.

S. **Facial myokymia**
Authorization of 12 months may be granted for the treatment of facial myokymia.

T. **Hirschsprung disease with internal sphincter achalasia**
Authorization of 12 months may be granted for the treatment of Hirschsprung’s disease with internal sphincter achalasia following endorectal pull through and the member is refractory to laxative therapy.

U. **Orofacial tardive dyskinesia**
Authorization of 12 months may be granted for the treatment of orofacial tardive dyskinesia when conventional therapies have been tried and failed (e.g., benzodiazepines, clozapine, or tetrabenazine).

V. **Painful bruxism**
Authorization of 12 months may be granted for the treatment of painful bruxism when the member has had an inadequate response to a night guard and has had an inadequate response to pharmacologic therapy such as diazepam.

W. **Palatal myoclonus**
Authorization of 12 months may be granted for the treatment of palatal myoclonus when the member has disabling symptoms (e.g., intrusive clicking tinnitus) who had an inadequate response to clonazepam, lamotrigine, carbamazepine or valproate.
X. **First bite syndrome**
Authorization of 12 months may be granted for the treatment of first bite syndrome when the member has failed relief from analgesics, antidepressants or anticonvulsants.

**Myobloc**

A. **Cervical dystonia**
Authorization of 12 months may be granted for treatment of cervical dystonia (e.g., torticollis) when there is sustained head torsion and/or tilt with limited range of motion and one 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. **Excessive salivation**

- Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

C. **Primary axillary and palmar hyperhidrosis**
Authorization of 12 months may be granted for treatment of primary axillary or palmar hyperhidrosis when all of the following criteria are met:
- Member is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines); and
- Significant disruption of professional and/or social life has occurred because of excessive sweating; and
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

D. **Upper limb spasticity**
Authorization of 12 months may be granted for treatment of upper limb spasticity.

**Dysport**

A. **Cervical dystonia**
Authorization of 12 months may be granted for treatment of cervical dystonia (e.g., torticollis) when there is sustained head torsion and/or tilt with limited range of motion.

B. **Upper limb spasticity**
Authorization of 12 months may be granted for treatment of upper limb spasticity.

C. **Lower limb spasticity**
Authorization of 12 months may be granted for treatment of lower limb spasticity.

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

E. **Hemifacial spasm**
Authorization of 12 months may be granted for treatment of hemifacial spasm.

F. **Chronic anal fissures**
Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first-line therapy such as topical calcium channel blockers or topical nitrates.

G. **Excessive salivation**
Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

H. Primary axillary hyperhidrosis
Authorization of 12 months may be granted for treatment of primary axillary hyperhidrosis when all of the following criteria are met:
- Member is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines); and
- Significant disruption of professional and/or social life has occurred because of excessive sweating; and
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

Xeomin

A. Cervical dystonia
Authorization of 12 months may be granted for treatment of cervical dystonia (e.g., torticollis) when there is sustained head torsion and/or tilt with limited range of motion and one 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.

B. Blepharospasm
Authorization of 12 months may be granted for treatment of blepharospasm when one 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

C. Upper limb spasticity
Authorization of 12 months may be granted for treatment of upper limb spasticity when one 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.

D. Excessive salivation
Authorization of 12 months may be granted for treatment of chronic sialorrhea when the member has been refractory to pharmacotherapy (e.g. anticholinergics).

Continuation of Therapy

A. All members (including new members) 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 member has achieved or maintained a reduction in monthly headache frequency since starting therapy with Botox

Botox, Dysport, Myobloc, and Xeomin are considered not medically necessary for members who do not meet the criteria set forth above.
Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

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

<table>
<thead>
<tr>
<th>PROCEDURES AND BILLING CODES</th>
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<tbody>
<tr>
<td><em><em>To report provider services, use appropriate CPT</em> codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.</em>*</td>
</tr>
<tr>
<td>• J0585 Injection, onabotulinumtoxinA (Botox), 1 unit</td>
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<tr>
<td>• J0586 Injection, abobotulinumtoxinA (Dysport), 5 units</td>
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<tr>
<td>• J0587 Injection, rimabotulinumtoxinB (Myobloc), 100 units</td>
</tr>
<tr>
<td>• J0588 Injection, incobotulinumtoxinA (Xeomin), 1 unit</td>
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</tbody>
</table>

REFERENCES

• Conrin L, Karp Bl, Alter K et al. Long Term Follow-up Botulinum Toxin Therapy for Focal Hand Dystonia: Outcome at 10 or More Years: Mov Disord. 2011 Mar; 26(4): 750–753.

POLICY HISTORY

Policy #: 05.01.02
Policy Creation: May 1991
Reviewed: January 2020
Revised: January 2020
Current Effective Date: January 1, 2020