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), Dysport (abobotulinumtoxinA) and Xeomin (incobotulinumtoxinA) are the preferred products. The criteria will require the use of the health plan's preferred products before the use of targeted product, Myobloc (rimabotulinumtoxinB), for an indication that is FDA-approved for the preferred product unless there are clinical circumstances that exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

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 spasticity (upper and/or lower limb) in patients 2 years of age and older
- 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. Safety and effectiveness have not been established in patients under age 18.
- 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 (ptyalism)
- 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

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 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 upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- Treatment of chronic sialorrhea in patients 2 years of age and older

Table. Botulinum Toxins

Medication	Generic Name
Preferred Products:	
Botox	onabotulinumtoxinA
Dysport	abobotulinumtoxinA
Xeomin	incobotulinumtoxinA
Targeted Product(s):	
Myobloc	rimabotulinumtoxinB

POLICY

Criteria for Initial Approval

Botox

A. Blepharospasm
Authorization of 12 months may be granted for treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

B. Cervical dystonia
Authorization of 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when there is abnormal placement of the head with limited range of motion in the neck.

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 experiences headaches lasting 4 hours or longer on at least 8 days per month
3. Member completed an adequate trial of (or has a contraindication to) 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, venlafaxine)
    - Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium)

- Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol)

4. Member has signs and symptoms consistent with chronic migraine diagnostic criteria as defined by the International Headache Society (IHS)

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 an anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).

E. Primary axillary, palmar, 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 oral 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 or lower limb spasticity

Authorization of 12 months may be granted for treatment of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

H. Urinary incontinence associated with a neurologic condition (e.g., 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]).

I. Achalasia

Authorization of 12 months may be granted for treatment of achalasia when the member has tried and failed or is a poor candidate for conventional therapy such as pneumatic dilation and surgical myotomy.

J. 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.

K. Essential tremor

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

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

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

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

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

P. 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

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

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

S. 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.

T. 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).

U. 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.

V. 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 clonazapam, lamotrigine, carbamazepine or valproate.

W. 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 adults with cervical dystonia (e.g., torticollis) when there is abnormal placement of the head with limited range of motion in the neck and one of the following criteria is met:

- The member is currently receiving treatment with Myobloc through health insurance, excluding if obtained as samples or via manufacturer's patient assistance programs.
- The member has had an inadequate response or an intolerable adverse event to all preferred products, Botox, Dysport and Xeomin.

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) and one of the following criteria is met:

- The member is currently receiving treatment with Myobloc through health insurance, excluding if obtained as samples or via manufacturer's patient assistance programs.
- The member has had an inadequate response or an intolerable adverse event to the preferred product, Xeomin.

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 oral 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 either as a primary diagnosis or as a symptom of a condition causing limb spasticity..

Dysport

A. Cervical dystonia

Authorization of 12 months may be granted for treatment of adults with cervical dystonia (e.g., torticollis) when there is abnormal placement of the head with limited range of motion in the neck.

B. Upper or lower limb spasticity

Authorization of 12 months may be granted for treatment of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

C. Blepharospasm

Authorization of 12 months may be granted for treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

D. Hemifacial spasm

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

E. 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.

F. 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).

G. 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 oral 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 abnormal placement of the head with limited range of motion in the neck.

B. Blepharospasm

Authorization of 12 months may be granted for treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

C. Upper limb spasticity

Authorization of 12 months may be granted for treatment of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

D. 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).

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; Myobloc 10,000 units; Dysport 1,500 units; Xeomin 400 units

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

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POLICY HISTORY

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