

# Botulinum toxins: abobotulinumtoxinA (Dysport®), incobotulinumtoxinA (Xeomin®), onabotulinumtoxinA (Botox®), rimabotulinumtoxinB (Myobloc®), and daxibotulinumtoxinA-lanm (Daxxify™)

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan will be used to determine your coverage.

## Administrative Process

Use for migraines, hyperhidrosis, chronic sialorrhea and off-label indications will not be covered without prior authorization from HealthPartners Pharmacy Administration.

Cosmetic use (including the treatment of glabellar/canthal lines or wrinkles) and other conditions not listed in this policy are not covered.

Quantity limits and frequency limits may apply to all claims.

If white bagging Botox is necessary, please contact Accredo at 1-844-516-3390.

## Coverage

**Botulinum toxin preparations are covered as follows based on indication:**

### Prevention of chronic migraine

#### Initial Authorizations:

Coverage for botulinum toxin preparations is subject to the indications listed below, and per your plan documents. Botox, Xeomin and Dysport require prior authorization but will generally be approved when the following criteria are met:

1. Prescribing by a headache specialist who has received training in the injection technique; **and**,
2. Patient must not be on concurrent CGRP antagonists for migraine prevention (Aimovig, Ajovy, Emgality, Vyepti, Nurtec ODT, or Qulipta) **and**,
3. Patient has chronic migraine (defined as 15 headache days/month lasting 4 hours a day); **and**,
4. Patient has tried and failed standard treatment, including at least three preventive drug therapies, meeting the following criteria:
  - A. Therapies must include at least three of the following five different drug categories: beta-blockers, calcium channel blockers, anticonvulsants, antidepressants, or CGRP antagonists (see examples in table below); **and**,
  - B. Failure of each therapy is defined as at least 12 weeks of treatment; **and**,
    - i. No reduction in migraine days compared to baseline; **or**,
    - ii. At least 1 migraine exacerbation requiring emergency room treatment or hospitalization while on therapy.

Drug Category	Example Agents
Beta-blockers	Metoprolol, propranolol, timolol
Calcium channel blockers	Verapamil, nifedipine
Anticonvulsants	Topiramate, valproate, gabapentin, Zonisamide
Antidepressants	Amitriptyline, nortriptyline, doxepin, venlafaxine
CGRP antagonists	Emgality, Ajovy, Aimovig, Vyepti, Qulipta

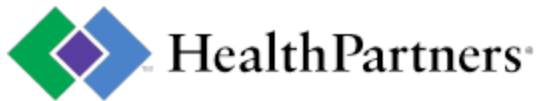
Initial authorization will be provided for 12 months.

Botox and Xeomin will be approved for a maximum of 200 units (200 billable HCPC units) per visit and at a maximum frequency of every 12 weeks for migraine.

Dysport will be approved for a maximum of 500 units (100 billable HCPC units) per visit and at a maximum frequency of every 12 weeks for migraine.

#### Reauthorizations:

1. Medical chart documentation that the medication is efficacious defined as a reduction of at least 2 migraine days per month from baseline; and,



2. Patient must not be on concurrent CGRP antagonists for migraine prevention (such as Aimovig, Ajovy, Emgality, Vyepti, Nurtec ODT, or Qulipta).

Reauthorizations will be provided for 12 months.

### **Severe axillary hyperhidrosis**

Botox and Xeomin use for hyperhidrosis requires prior authorization. Botox is FDA-approved for use in severe axillary hyperhidrosis. HealthPartners covers Botox and Xeomin for severe focal (e.g., axillary/palmar/plantar) hyperhidrosis cases as those where non-pharmacological therapies (e.g., hygiene and avoidance of stimulating factors) and the proper use of topical preparations (aluminum chloride 20% solution) have **both** failed to improve the activities of daily living in affected members. Coverage for all other preparations is off label, requires prior authorization, and will be reviewed on a case by case basis.

### **Cervical dystonia**

All preparations are covered and do not require prior authorization.

### **Upper and lower limb spasticity**

Botox, Dysport, and Xeomin do not require a prior authorization for this use. All other preparations are off label and not covered for the listed diagnosis.

### **Strabismus**

Botox and Xeomin do not require a prior authorization for this use. All other preparations are off label and not covered for the listed diagnosis.

### **Blepharospasm**

Botox and Xeomin do not require a prior authorization for this use. All other preparations are off label and not covered for the listed diagnosis.

### **Urinary incontinence and overactive bladder**

Botox and Xeomin do not require a prior authorization for this use. All other preparations are off label and not covered for the listed diagnosis.

### **Chronic sialorrhea**

All agents require a prior authorization for this use. Xeomin and Myobloc will generally be approved for chronic sialorrhea in adult patients resulting from Parkinson's disease, atypical Parkinsonism, stroke, or traumatic brain injury when present for at least three months. Xeomin will generally be approved for chronic sialorrhea in pediatric patients ages 2-17. All other preparations are off label and not covered for the listed diagnosis.

### **Indications that are not covered**

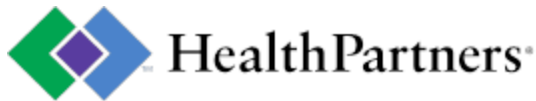
1. Cosmetic use (e.g., the treatment of glabellar/canthal lines or wrinkles) is not considered medically necessary.
2. Other conditions not listed in this policy.

### **Botulinum toxin Quantity Limits**

All requests for doses exceeding the FDA-approved regimen will not be covered.

### **Definitions**

**Botulinum toxin** is an acetylcholine release inhibitor and a neuromuscular blocking agent. It is a purified neurotoxin that acts at the neuromuscular junction to produce flaccid paralysis. Each preparation has the following indications and dosing:



**Botox (OnabotulinumtoxinA)**

- 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 urinary incontinence due to detrusor over activity 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.
- 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 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, excluding spasticity caused by cerebral palsy
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- Treatment of blepharospasm associated with dystonia in patients 12 years of age
- Treatment of strabismus in patients 12 years of age

Safety and effectiveness have not been established for:

- Prophylaxis of episodic migraine (14 headache days or fewer per month)
- Treatment of hyperhidrosis in body areas other than axillary.

**Dysport (AbobotulinumtoxinA)**

- The treatment of adults with cervical dystonia patients
- The treatment of limb spasticity in adults
- The 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, excluding spasticity caused by cerebral palsy

**MyoBloc (RimabotulinumtoxinB)**

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

**Xeomin (IncobotulinumtoxinA)**

**Treatment of upper limb spasticity in patients 2 years of age and older**

- Treatment of adults with cervical dystonia
- Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA (Botox)
- Treatment of chronic sialorrhea in patients 2 years of age and older

**Daxxify (daxibotulinumtoxinA-lanm)**

- Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients
- The treatment of adults with cervical dystonia patients

**Codes**

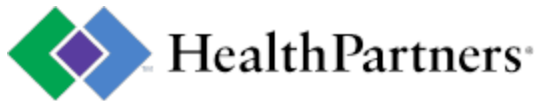
*If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.*

**HCPCS Codes**

Codes	Description
J0585	Injection, onabotulinumtoxinA, 1 unit (Botox)
J0586	Injection, abobotulinumtoxinA, 5 units (Dysport)
J0587	Injection, rimabotulinumtoxinB, 100 units (Myobloc)
J0588	Injection, incobotulinumtoxinA, 1 unit (Xeomin)
J0589	Injection, daxibotulinumtoxinA-lanm, 1 unit

**NDC Codes**

Codes	Description
00023114501	Botox 100UNIT Solution Reconstituted

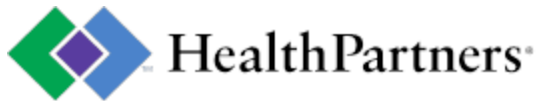


00023392102	Botox 200UNIT Solution Reconstituted
00299596230	Dysport 300UNIT Solution Reconstituted
15054053006	Dysport 300UNIT Solution Reconstituted
15054050001	Dysport 500UNIT Solution Reconstituted
10454071210	Myobloc 10000UNIT/2ML Solution
10454071010	Myobloc 2500UNIT/0.5ML Solution
10454071110	Myobloc 5000UNIT/ML Solution
00259161001	Xeomin 100UNIT Solution Reconstituted
00259162001	Xeomin 200UNIT Solution Reconstituted
00259160501	Xeomin 50UNIT Solution Reconstituted
7296011201	Daxxify 100UNIT Solution Reconstituted
7296011101	Daxxify 50UNIT Solution Reconstituted

#### ICD-10-CM Codes

The following diagnosis codes do not require prior authorization for any botulinum toxin products. Quantity limits may apply.

ICD10	Description
G04.1	Tropical spastic paraplegia
G24.01	Drug induced subacute dyskinesia
G24.02	Drug induced acute dyskinesia
G24.09	Other drug induced dystonia
G24.1	Genetic torsion dystonia
G24.2	Idiopathic nonfamilial dystonia
G24.4	Idiopathic orofacial dystonia
G24.8	Other dystonia
G24.9	Dystonia, unspecified
G25.0 – G25.2	Other extrapyramidal and movement disorders
G25.3	Myoclonus
G25.89	Other specified extrapyramidal and movement disorders
G51.0	Bell's palsy
G51.1	Geniculate ganglionitis
G51.2	Melkersson's syndrome
G51.31	Clonic hemifacial spasm, right
G51.32	Clonic hemifacial spasm, left
G51.33	Clonic hemifacial spasm, bilateral
G51.39	Conic hemifacial spasm, unspecified
G51.4	Facial myokymia
G51.8	Other disorders of facial nerve
G51.9	Disorder of facial nerve, unspecified
G82.20-G83.34	Paraplegia (paraparesis) and quadriplegia (quadriparesis)
G83.4	Cauda equine syndrome
I69	Sequelae of cerebrovascular disease
J38.5	Laryngeal spasm
K22.0	Achalasia of cardia
K59.4	Anal spasm
K60.1	Chronic anal fissure
K60.2	Anal fissure, unspecified
R25.0	Abnormal head movements
R25.1	Tremor, unspecified
R25.2	Cramp and spasm
R25.3	Fasciculation
R25.8	Other abnormal involuntary movements
R25.9	Unspecified abnormal involuntary movements
R29.891	Ocular torticollis
R49.0	Dysphonia
R49.8	Other voice and resonance disorders
R49.9	Unspecified voice and resonance disorder
S04.011S	Injury of cranial nerve, sequela
S04.50XA	Injury of facial nerve, unspecified side, initial encounter



S04.51XA	Injury of facial nerve, right side, initial encounter
S04.52XA	Injury of facial nerve, left side, initial encounter
S06.0x0S – S06.9x9S	Intracranial injury, sequela
S14.0xxS – S14.9xxS, S24.0xxS- S24.9xxS, S34.01xS- S34.9xxS	Injury of nerves and spinal cord, sequela

**For Botox (J0585) and Xeomin (J0588), the following codes do not require prior authorization:**

Codes	Description
N31.0	Uninhibited neuropathic bladder, not elsewhere classified
N31.1	Reflex neuropathic bladder, not elsewhere classified
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder
N36.44	Muscular disorders of urethra
N39.41	Urge incontinence
N39.46	Mixed incontinence
H49.00-H51.9	Strabismus and other disorders of binocular eye movements
G24.5	Blepharospasm

**For Botox, Dysport and Xeomin (J0585, J0586, J0588), the following codes do not require prior authorization:**

Codes	Description
G11.4	Hereditary spastic paraplegia (limb spasticity due to)
G24.3	Spasmodic torticollis
G35	Multiple sclerosis (limb spasticity due to)
G36.0-G37.9	Other acute disseminated and demyelinating diseases of CNS (limb spasticity due to)
G80.0-G80.9	Cerebral palsy
G81.10-G81.14	Spastic hemiplegia

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**All other diagnosis codes require prior authorization.**

## Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria may not apply to Medicare Products if Medicare requires different coverage. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7979 or 1-800-233-9645.

Approved by Pharmacy & Therapeutics Committee 10/01/1996; Revised 11/11/2003, 12/19/2008, 5/25/2011, 9/1/2011, 1/1/2014; 11/7/2016, 8/14/2017, 5/7/2018, 8/13/2018, 5/6/2019, 10/30/2019, 4/6/2020; 1/6/2021, 12/1/2021, 10/1/2022, 12/22/2022, 04/01/2023; Annual Review 11/11/2003, 11/1/2004, 6/1/2005, 7/1/2006, 8/1/2007, 12/19/2008, 6/1/2009, 5/20/2010, 5/25/2011, 9/1/2011, 9/1/2012, 7/1/2013, 1/1/2014, 10/1/2015, 5/1/2016, 4/1/2017, 4/1/2018, 5/1/2018, 5/1/2019, 4/1/2020, 4/1/2021, 4/1/2022, 4/1/2023, 4/1/2024

## References

1. Botox prescribing information. Allergan, Inc. 5/2018.
2. MyoBloc prescribing information. Solstice Neurosciences, Inc. 1/2012.
3. Dysport prescribing information. Ipsen Biopharm Ltd. 6/2017.
4. Xeomin prescribing information. Merz Pharmaceuticals, LLC. 7/2018.
5. Daxxify prescribing information. Revance Therapeutics, Inc. 9/2022.