

Botulinum Toxins

HCPCS: J0585 Injection, onabotulinumtoxin A, 1 unit (Botox), J0586 Injection, abobotulinumtoxin A, 5 units (Dysport), J0587 Injection, rimabotulinumtoxin B, 100 units (Myobloc), J0588 Injection, incobotulinumtoxin A, 1 unit (Xeomin)

LOB	MCAL
Duration of Approval:	One year
Quantity Limit:	Per FDA Approved/Compendia Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

- Botox (onabotulinumtoxin A)
- Dysport (abobotulinumtoxin A)
- Myobloc (rimabotulinumtoxin B)
- Xeomin (incobotulinum toxin type A)

PA CRITERIA FOR APPROVAL:

New Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) OR a compendia-supported (Drugdex or AHFS) indication
AND
2. The medication was prescribed or recommended by a dermatologist, ear, nose and throat (ENT) physician, gastroenterologist, neurologist, ophthalmologist, orthopedist, pain management specialist, physiatrist, rheumatologist, surgeon or urologist
AND
3. **For diagnosis of overactive bladder (OAB) (for Botox, Myobloc [off-label]):** The member meets **ALL** of the following (a-b):
 - a. The member has symptoms of urge urinary incontinence, urgency and frequency
 - b. The member has a history of failure, contraindication or reasons for intolerance to at least ONE anticholinergic medication (such as oxybutynin, tolterodine, darifenacin, fesoterodine, solifenacin or trospium) **OR** beta-3 adrenergic agonists (such as mirabegron)**OR**
4. **For diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury [SCI], multiple sclerosis [MS]) (for Botox):** The member has a history of failure, contraindication or reasons for intolerance to at least ONE anticholinergic medication (such as oxybutynin, fesoterodine or solifenacin) **OR** beta-3 adrenergic agonists (such as mirabegron)
OR
5. **For diagnosis of sialorrhea (for Botox [off-label], Myobloc, Xeomin):** The member has a history of failure, contraindication or reasons for intolerance to medical treatment such as glycopyrrolate (**Note:** glycopyrrolate is FDA-indicated to reduce chronic severe drooling in patients aged 3–16 years with neurologic conditions associated with problem drooling)
OR
6. **For diagnosis of achalasia (for Botox [off-label], Dysport [off-label]):** The member is unfit for definitive therapies such as laparoscopic Heller myotomy (LHM), pneumatic dilation (PD) or peroral endoscopic myotomy (POEM)
OR
7. **For diagnosis of chronic anal fissure (for Botox [off-label]):** The member has a history of failure, contraindication or reasons for intolerance to topical nitrate (nitroglycerin ointment)
OR
8. **For diagnosis of prevention of chronic migraine (for Botox):** The member meets **ALL** of the following (a-c):
 - a. Documented headaches of ≥ 15 days per month lasting four hours or longer for at least three months
 - b. Chart notes showing the member has ALL of the following (1 and 2):

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- 1) Headache symptoms, as indicated by **two or more** of the following:
 - Aggravation by or causing avoidance of routine physical activity
 - Moderate or severe pain intensity
 - Pulsating quality
 - Unilateral location
- 2) Migraine-associated symptoms, as indicated by **one or more** of the following:
 - Nausea or vomiting
 - Photophobia and phonophobia
- c. The member has a history of failure of two migraine preventive therapies (from different classes of medication), such as:
 - beta-blockers (atenolol, bisoprolol, metoprolol, timolol, propranolol or nadolol)
 - angiotensin-converting enzyme (ACE) inhibitor (lisinopril, enalapril)
 - angiotensin II receptor blocker (ARB) (candesartan)
 - calcium channel blocker (verapamil)
 - tricyclic antidepressants (amitriptyline, nortriptyline)
 - serotonin-norepinephrine reuptake inhibitors (SNRI) (venlafaxine or duloxetine)
 - selective-serotonin reuptake inhibitors (SSRI) (fluoxetine)
 - anticonvulsants (divalproex, levetiracetam, topiramate, valproate sodium)
 - calcitonin gene-related peptide (CGRP) receptor antagonist (Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti)

Note: Only propranolol, divalproex, topiramate, Aimovig, Ajovy, Emgality, Nurtec, Qulipta and Vyepti are FDA-indicated for migraine prevention. Only include FDA-indicated drugs in the denial rationale.

Note: Aimovig, Qulipta and Vyepti require PA under Medi-Cal Rx.

OR

9. **For diagnosis of primary axillary hyperhidrosis (for Botox, Myobloc [off-label]):** The member meets **ALL** of the following (a-b):
 - a. Hyperhidrosis Disease Severity Scale (HDSS) score of 2 or more (see [Table 1.](#))
 - b. The member has a history of failure, contraindication or reasons for intolerance to at least one month duration on topical agents (such as Drysol or Xerac AC) as evidenced by no improvement on HDSS score (**Note:** Drysol and Xerac AC are not covered under MediCal Rx)

OR

10. **For diagnosis of Raynaud's phenomenon (for Botox [off-label]):** The member meets **ALL** of the following (a-c):
 - a. The member has severe disease with pain and/or functional impairment associated with scleroderma, digital ulcerations or gangrene
 - b. Absence of vascular obstruction on Doppler ultrasound
 - c. The member has a history of failure, contraindication or reasons for intolerance to at least TWO of the following vasodilator therapies:
 - 1) Calcium channel blockers (CCB) such as amlodipine, nifedipine
 - 2) Phosphodiesterase type 5 (PDE5) inhibitors such as sildenafil, tadalafil
 - 3) Angiotensin II receptor blockers (ARBs) such as losartan
 - 4) Selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine
 - 5) Prostaglandins such as epoprostenol, iloprost and treprostinil
 - 6) Endothelin receptor antagonist such as bosentan
 - 7) Topical nitrates such as nitroglycerin ointment

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Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under references) OR a compendia-supported (Drugdex or AHFS) indication
AND
2. The medication was prescribed or recommended by a dermatologist, ENT physician, gastroenterologist, neurologist, ophthalmologist, orthopedist, pain management specialist, physiatrist, rheumatologist, surgeon or urologist
AND
3. Documentation provided showing a positive response to therapy

EXCLUSIONS

- Botox Cosmetic is not a covered benefit
- Botulinum Toxins A & B for glabellar lines is not a covered benefit (cosmetic condition)

Table 1.

Hyperhidrosis Disease Severity Scale	
Patient self-assessment to the question “How would you rate the severity of your hyperhidrosis?”	
HDSS Score	Patient’s Response:
1	My sweating is never noticeable and never interferes with my daily activities
2	My sweating is tolerable but sometimes interferes with my daily activities
3	My sweating is barely tolerable and frequently interferes with my daily activities
4	My sweating is intolerable and always interferes with my daily activities

OTHER INFORMATION:

HCPCS	Description	Brand name
J0585	Injection, onabotulinumtoxin A, 1 unit	Botox
J0586	Injection, abobotulinumtoxin A, 5 units	Dysport
J0587	Injection, rimabotulinumtoxin B, 100 units	Myobloc
J0588	Injection, Incobotulinumtoxin A, 1 unit	Xeomin

DOSAGE & ADMINISTRATION

Drug	Dosing
Botox	Raynaud’s phenomenon (**off label**): up to 100 units per hand per 12 weeks

REFERENCES:

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2. Dysport Prescribing Information. www.dysportusa.com/PI. 09/2023
3. Xeomin Prescribing Information. dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ccdc3aae-6e2d-4cd0-a51c-8375bfee9458&type=display. 07/2024.
4. Myobloc Prescribing Information. www.myoblochcp.com/files/MYOBLOC_PI.pdf. 03/2021.
5. International Headache Society (IHS) Classification ICHD-3. ihs-headache.org/wp-content/uploads/2025/04/ICHD-3-Cephalalgia-2018-issue-1.pdf
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8. Pinto-Pulido EL, Polo-Rodriguez I, Garcia-Verdu E, et al. Botulinum toxin for Raynaud’s phenomenon: A decade of real-world evidence. Journal of the American Academy of Dermatology (JAAD). 2025. 92(1): P173-175. Botulinum

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[toxin for Raynaud's phenomenon: A decade of real-world evidence](#)

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10. Vaezi MF, Pandolfino JE, Yadlapati RH, et al. ACG Clinical Guidelines: Diagnosis and Management of Achalasia. Am J Gastroenterol 2020;115:1393-1411. www.giboardreview.com/wp-content/uploads/2020/10/Guidelines-Achalasia-2020-ACG.pdf

P&T APPROVAL HISTORY

May 2011 P&T Drug Review.

UMC Review: 4/2026