

Jurisdiction Specific Medicare Part B Botulinum Toxins

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Botox	onabotulinumtoxin A
Daxxify	daxibotulinumtoxinA-lanm
Myobloc	rimabotulinumtoxin B
Dysport	abobotulinumtoxin A
Xeomin	incobotulinumtoxin A

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Migraine headache
- Cervical dystonia
- Spasticity
- Blepharospasm
- Hemifacial spasm
- Hyperhidrosis
- Overactive bladder
- Achalasia/Cardiospasm
- Duane's Syndrome

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Authorization of 6 months may be granted for the requested medication when all of the following are met:

- The patient is not currently receiving botulinum toxin treatment.
- The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57185]).
- The patient has been unresponsive to conventional treatments such as other medications or physical therapy. Exceptions to this requirement are: focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, dysphonia.
- The requested medication is FDA-approved for the requested indication, unless the provider can provide a valid and documented reason why the medication needs to be used off-label
- If the patient has any of the following indications, they must meet the associated criteria:
 - For Duane's Syndrome, the requested medication will be used for medial rectus weakness only
 - For overactive bladder, the patient experiences urge urinary incontinence, urgency, and frequency and the patient has had an inadequate response or intolerance to anticholinergic medications
 - For achalasia/cardiospasm, the patient has either failed conventional therapy, the patient is at high risk of complications from pneumatic dilation or surgical myotomy, the patient has refused surgical myotomy or balloon dilation in preference to a less risky procedure, prior myotomy or dilation has failed, prior dilation caused esophageal perforation, or patient has epiphrenic diverticulum or hiatal hernia
 - For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
 - For strabismus, the patient does not have restrictive strabismus, chronic paralytic strabismus (except to reduce antagonist contracture in conjunction with surgical repair) or deviations over 50 prism diopters.

Authorization of 6 months may be granted for the requested medication when all of the following are met:

- The patient is currently receiving botulinum toxin treatment and has experienced a positive response.
- The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57185]).
- The patient has been unresponsive to conventional treatments such as other medications or physical therapy. Exceptions to this requirement are: focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, dysphonia.
- The requested medication is FDA-approved for the requested indication, unless the provider can provide a valid and documented reason why the medication needs to be used off-label
- If the patient has any of the following indications, they must meet the associated criteria:
 - For Duane's Syndrome, the requested medication will be used for medial rectus weakness only

- For overactive bladder, the patient experiences urge urinary incontinence, urgency, and frequency and the patient has had an inadequate response or intolerance to anticholinergic medications
- For achalasia/cardiospasm, the patient has either failed conventional therapy, the patient is at high risk of complications from pneumatic dilation or surgical myotomy, the patient has refused surgical myotomy or balloon dilation in preference to a less risky procedure, prior myotomy or dilation has failed, prior dilation caused esophageal perforation, or patient has epiphrenic diverticulum or hiatal hernia
- For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
- For strabismus, the patient does not have restrictive strabismus, chronic paralytic strabismus (except to reduce antagonist contracture in conjunction with surgical repair) or deviations over 50 prism diopters.

Authorization of 1 month may be granted for the requested medication when all of the following are met:

- The patient is currently receiving botulinum toxin treatment and has not experienced a positive response.
- The patient is not receiving the maximum dose which could be utilized for the size of the muscle being treated and the intent is for the maximum dose to be attempted based on patient-specific factors.
- The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57185]).
- The patient has been unresponsive to conventional treatments such as other medications or physical therapy. Exceptions to this requirement are: focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, dysphonia.
- The requested medication is FDA-approved for the requested indication, unless the provider can provide a valid and documented reason why the medication needs to be used off-label
- If the patient has any of the following indications, they must meet the associated criteria:
 - For Duane's Syndrome, the requested medication will be used for medial rectus weakness only
 - For overactive bladder, the patient experiences urge urinary incontinence, urgency, and frequency and the patient has had an inadequate response or intolerance to anticholinergic medications
 - For achalasia/cardiospasm, the patient has either failed conventional therapy, the patient is at high risk of complications from pneumatic dilation or surgical myotomy, the patient has refused surgical myotomy or balloon dilation in preference to a less risky procedure, prior myotomy or dilation has failed, prior dilation caused esophageal perforation, or patient has epiphrenic diverticulum or hiatal hernia
 - For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
 - For strabismus, the patient does not have restrictive strabismus, chronic paralytic strabismus (except to reduce antagonist contracture in conjunction with surgical repair) or deviations over 50 prism diopters.

Reference number(s)
5524-A

Authorization of 1 month may be granted for the requested medication when all of the following are met:

- The patient is currently receiving botulinum toxin treatment and has not experienced a positive response.
- The patient is receiving the maximum dose which could be utilized for the size of the muscle being treated.
- An alternate botulinum toxin is being requested.
- The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57185]).
- The patient has been unresponsive to conventional treatments such as other medications or physical therapy. Exceptions to this requirement are: focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, dysphonia.
- The requested medication is FDA-approved for the requested indication, unless the provider can provide a valid and documented reason why the medication needs to be used off-label
- If the patient has any of the following indications, they must meet the associated criteria:
 - For Duane's Syndrome, the requested medication will be used for medial rectus weakness only
 - For overactive bladder, the patient experiences urge urinary incontinence, urgency, and frequency and the patient has had an inadequate response or intolerance to anticholinergic medications
 - For achalasia/cardiospasm, the patient has either failed conventional therapy, the patient is at high risk of complications from pneumatic dilation or surgical myotomy, the patient has refused surgical myotomy or balloon dilation in preference to a less risky procedure, prior myotomy or dilation has failed, prior dilation caused esophageal perforation, or patient has epiphrenic diverticulum or hiatal hernia
 - For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
 - For strabismus, the patient does not have restrictive strabismus, chronic paralytic strabismus (except to reduce antagonist contracture in conjunction with surgical repair) or deviations over 50 prism diopters.

References

1. Botulinum Toxins LCD (L35170) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 18, 2024.
2. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57185) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 19, 2024.