

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	onabotulinumtoxinA
Dysport	abobotulinumtoxinA
Myobloc	rimabotulinumtoxinB
Xeomin	incobotulinumtoxinA

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.

- Spasticity
- Blepharospasm and/or hemifacial spasm
- Achalasia
- Anal fissure
- Hyperhidrosis
- Sialorrhea
- Urinary incontinence
- Chronic tension-type headache
- Chronic migraine headache

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.

Exclusions

Coverage will not be provided for cosmetic use.

Coverage Criteria

Spasticity

Authorization of 12 months may be granted for treatment of spasticity when both of the following criteria are met:

- The member has a covered spastic condition listed in article A52848 under “ICD-10-CM Codes that Support Medical Necessity”.
- The member is new to treatment with botulinum toxin therapy.

Authorization of 12 months may be granted for treatment of spasticity when all of the following criteria are met:

- The member has a covered spastic condition listed in article A52848 under “ICD-10-CM Codes that Support Medical Necessity”.
- The request is for treatment of lower limb spasticity and the requested product is either Botox or Dysport.
- The member is new to treatment with botulinum toxin therapy.

Authorization of 12 months may be granted for treatment of spasticity when both of the following criteria are met:

- The member has a covered spastic condition listed in article A52848 under “ICD-10-CM Codes that Support Medical Necessity”.
- The member is currently receiving treatment with a botulinum toxin and is experiencing a positive response.

Authorization of 12 months may be granted for treatment of spasticity when both of the following criteria are met:

- The member has a covered spastic condition listed in article A52848 under “ICD-10-CM Codes that Support Medical Necessity”.
- The member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Blepharospasm and Hemifacial Spasm

Authorization of 12 months may be granted for treatment of blepharospasm or hemifacial spasm when the member is new to treatment with botulinum toxin therapy.

Authorization of 12 months may be granted for treatment of blepharospasm or hemifacial spasm when the member is currently receiving treatment with a botulinum toxin and is experiencing a positive response.

Authorization of 12 months may be granted for treatment of blepharospasm or hemifacial spasm when the member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Achalasia

Authorization of 12 months may be granted for treatment of achalasia when the member is new to therapy with a botulinum toxin and any of the following criteria are met:

- The member has not responded satisfactorily to conventional therapy.
- The member is at high risk of complication from pneumatic dilation or surgical myotomy.
- The member has experienced treatment failure with pneumatic dilation or surgical myotomy.
- The member experienced perforation from pneumatic dilation.
- The member has an epiphrenic diverticulum or hiatal hernia.
- The member has esophageal varices.

Authorization of 12 months may be granted for treatment of achalasia when the member is currently receiving therapy and experiencing a positive response with a botulinum toxin and any of the following criteria are met:

- The member has not responded satisfactorily to conventional therapy.
- The member is at high risk of complication from pneumatic dilation or surgical myotomy.
- The member has experienced treatment failure with pneumatic dilation or surgical myotomy.
- The member experienced perforation from pneumatic dilation.
- The member has an epiphrenic diverticulum or hiatal hernia.
- The member has esophageal varices.

Authorization of 12 months may be granted for treatment of achalasia when the member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin and any of the following criteria are met:

- The member has not responded satisfactorily to conventional therapy.
- The member is at high risk of complication from pneumatic dilation or surgical myotomy.
- The member has experienced treatment failure with pneumatic dilation or surgical myotomy.
- The member experienced perforation from pneumatic dilation.

- The member has an epiphrenic diverticulum or hiatal hernia.
- The member has esophageal varices.

Anal Fissure

Authorization of 12 months may be granted for treatment of chronic anal fissures when both of the following criteria are met:

- The member has not responded satisfactorily to conventional therapy.
- The member is new to treatment with botulinum toxin therapy.

Authorization of 12 months may be granted for treatment of chronic anal fissures when both of the following criteria are met:

- The member has not responded satisfactorily to conventional therapy.
- The member is currently receiving botulinum toxin therapy and the member is experiencing a positive response.

Authorization of 12 months may be granted for treatment of chronic anal fissures when both of the following criteria are met:

- The member has not responded satisfactorily to conventional therapy.
- The member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Hyperhidrosis

Authorization of 12 months may be granted for treatment of primary focal hyperhidrosis when all of the following criteria are met:

- The member has experienced focal, visible, severe sweating of at least six months duration without apparent cause.
- The hyperhidrosis meets at least TWO of the following characteristics:
 - Bilateral and relatively symmetric hyperhidrosis
 - Significant impairment of daily activities
 - Age of onset less than 25 years
 - Family history of hyperhidrosis
 - Cessation of focal sweating during sleep
- The member is requesting treatment with Botox or Myobloc.
- The member is new to treatment with a botulinum toxin.

Authorization of 12 months may be granted for treatment of primary focal hyperhidrosis when all of the following criteria are met:

- Prior to treatment with botulinum toxin, the member experienced focal, visible, severe sweating of at least six months duration without apparent cause.
- The hyperhidrosis meets at least TWO of the following characteristics:
 - Bilateral and relatively symmetric hyperhidrosis
 - Significant impairment of daily activities
 - Age of onset less than 25 years
 - Family history of hyperhidrosis
 - Cessation of focal sweating during sleep
- The member is requesting treatment with Botox or Myobloc.
- The member is currently receiving treatment with an approvable botulinum toxin and is experiencing a positive response.

Authorization of 12 months may be granted for treatment of primary focal hyperhidrosis when all of the following criteria are met:

- Prior to treatment with botulinum toxin, the member experienced focal, visible, severe sweating of at least six months duration without apparent cause.
- The hyperhidrosis meets at least TWO of the following characteristics:
 - Bilateral and relatively symmetric hyperhidrosis
 - Significant impairment of daily activities
 - Age of onset less than 25 years
 - Family history of hyperhidrosis
 - Cessation of focal sweating during sleep
- The member is currently receiving treatment with an approvable botulinum toxin (Botox or Myobloc) and is not experiencing a positive response after two consecutive treatment sessions and the provider would like to attempt therapy with a different approvable botulinum toxin (either Botox or Myobloc).

Sialorrhea

Authorization of 12 months may be granted for treatment of sialorrhea when all of the following criteria are met:

- The condition is due to motor neuron disease or Parkinson's disease.
- The member meets one of the following:
 - The member has failed to respond to a reasonable trial of traditional therapies (e.g., anticholinergics or speech therapy)
 - The member has a contraindication to or cannot tolerate anticholinergic therapy.
- The member is new to treatment with a botulinum toxin.

Authorization of 12 months may be granted for treatment of sialorrhea when all of the following criteria are met:

- The condition is due to motor neuron disease or Parkinson’s disease.
- The member meets one of the following:
 - The member has failed to respond to a reasonable trial of traditional therapies (e.g., anticholinergics or speech therapy)
 - The member has a contraindication to or cannot tolerate anticholinergic therapy.
- The member is currently receiving treatment with a botulinum toxin and experiencing a positive response.

Authorization of 12 months may be granted for treatment of sialorrhea when all of the following criteria are met:

- The condition is due to motor neuron disease or Parkinson’s disease.
- The member meets one of the following:
 - The member has failed to respond to a reasonable trial of traditional therapies (e.g., anticholinergics or speech therapy)
 - The member has a contraindication to or cannot tolerate anticholinergic therapy.
- The member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Urinary Incontinence Due to Detrusor Activity

Authorization of 12 months may be granted for treatment of urinary incontinence when both of the following criteria are met:

- The requested drug will be used to treat urinary incontinence due to neurogenic detrusor overactivity (e.g., spinal cord injuries or neurological diseases).
- The member is new to treatment with a botulinum toxin.

Authorization of 12 months may be granted for treatment of urinary incontinence when both of the following criteria are met:

- The requested drug will be used to treat urinary incontinence due to neurogenic detrusor overactivity (e.g., spinal cord injuries or neurological diseases).
- The member is currently receiving treatment with a botulinum toxin and experiencing a positive response.

Authorization of 12 months may be granted for treatment of urinary incontinence when both of the following criteria are met:

- The requested drug will be used to treat urinary incontinence due to neurogenic detrusor overactivity (e.g., spinal cord injuries or neurological diseases).

- The member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Overactive Bladder with Urge Urinary Incontinence

Authorization of 12 months may be granted for treatment of urge urinary incontinence when all of the following criteria are met:

- The requested drug will be used to treat overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in members 5 years of age and older.
- The member has experienced an inadequate response or intolerance to an anticholinergic medication.
- The member is new to treatment with a botulinum toxin and the requested drug is Botox.

Authorization of 12 months may be granted for treatment of urge urinary incontinence when all of the following criteria are met:

- The requested drug will be used to treat overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in members 5 years of age and older.
- The member has experienced an inadequate response or intolerance to an anticholinergic medication.
- The member is currently receiving treatment with a botulinum toxin and experiencing a positive response.

Authorization of 12 months may be granted for treatment of urge urinary incontinence when all of the following criteria are met:

- The requested drug will be used to treat overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in members 5 years of age and older.
- The member experienced an inadequate response or intolerance to an anticholinergic medication.
- The member is not treatment naïve to botulinum toxins and failed to respond to two consecutive treatment sessions with Botox.
- The member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Tension-Type Headache

Authorization of 12 months may be granted for treatment of tension-type headaches when all of the following criteria are met:

- Prior to therapy, the member experienced chronic daily headaches, defined as headaches occurring for more than 15 days per month lasting more than four hours per day for a period of at least three months.
- Prior to therapy, the member experienced significant disability due to headaches.
- The condition is refractory to the standard and usual conventional therapy.
- The member is new to treatment with a botulinum toxin.

Authorization of 12 months may be granted for treatment of tension-type headaches when all of the following criteria are met:

- Prior to therapy, the member experienced chronic daily headaches, defined as headaches occurring for more than 15 days per month lasting more than four hours per day for a period of at least three months.
- Prior to therapy, the member experienced significant disability due to headaches.
- The condition is refractory to the standard and usual conventional therapy.
- The member is receiving treatment with a botulinum toxin and the member is experiencing a decrease in the number and frequency of headaches and an improvement in function.

Authorization of 12 months may be granted for treatment of tension-type headaches when all of the following criteria are met:

- Prior to therapy, the member experienced chronic daily headaches, defined as headaches occurring for more than 15 days per month lasting more than four hours per day for a period of at least three months.
- Prior to therapy, the member experienced significant disability due to headaches.
- The condition is refractory to the standard and usual conventional therapy.
- The member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Migraine Headache

Authorization of 12 months may be granted for treatment of migraine headaches when all of the following criteria are met:

- Prior to therapy, the member experienced chronic daily headaches, defined as headaches occurring for more than 15 days per month lasting more than four hours per day for a period of at least three months. At least eight of the headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment.
- Prior to therapy, the member experienced significant disability due to headaches.
- The condition is refractory to the standard and usual conventional therapy.
- The member is new to treatment with a botulinum toxin.

Authorization of 12 months may be granted for treatment of migraine headaches when all of the following criteria are met:

- Prior to therapy, the member experienced chronic daily headaches, defined as headaches occurring for more than 15 days per month lasting more than four hours per day for a period of at least three months. At least eight of the headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment.
- Prior to therapy, the member experienced significant disability due to headaches.
- The condition is refractory to the standard and usual conventional therapy.
- The member is receiving treatment with a botulinum toxin and the member is experiencing a decrease in the number and frequency of headaches and an improvement in function.

Authorization of 12 month may be granted for treatment of migraine headaches when all of the following criteria are met:

- Prior to therapy, the member experienced chronic daily headaches, defined as headaches occurring for more than 15 days per month lasting more than four hours per day for a period of at least three months. At least eight of the headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment.
- Prior to therapy, the member experienced significant disability due to headaches.
- The condition is refractory to the standard and usual conventional therapy.
- The member is not experiencing a positive response to the prescribed botulinum toxin after two consecutive treatment sessions and the provider would like to attempt therapy with a different botulinum toxin.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Botulinum Toxins LCD (L33646) Version R13. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 18, 2024.
2. Botulinum Toxins Billing and Coding Article (A52848) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 18, 2024.