Reference number(s)
2170-A

JURISDICTION SPECIFIC MEDICARE PART B

BOTOX (onabotulinumtoxin A)
MYOBLOC (rimabotulinumtoxin B)
DYSPORT (abobotulinumtoxin A)
XEOMIN (incobotulinumtoxin A)

POLICY

I. 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.

The list of covered indications is determined by ICD-10 code and is prohibitively long to include here. A complete list can be found at https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. A limited selection of indications are listed below:

A. Migraine headache
B. Cervical dystonia
C. Spasticity
D. Blepharospasm
E. Hemifacial spasm
F. Hyperhidrosis
G. Overactive bladder
H. Achalasia/Cardiospasm
I. Duane's Syndrome

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Type of botulinum toxin used: Botox, Dysport, Xeomin or Myobloc *(Note: It is the responsibility of the provider to use each drug in accordance with FDA approved indications unless there is a valid and documents reason stating why the unapproved/off label form is used.)*
B. Strength of toxin used
C. Covered diagnosis. However, when a form of botulinum toxin is used for an indication that is not a listed indication in the AHFS, a physician statement in the medical record stating the reason(s) why the unapproved form was used is also required).

D. A statement that traditional methods of treatment has been tried and proven unsuccessful. Exceptions to this requirement are: focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, dysphonia
E. Dosage used in the injections
F. Support for the medical necessity of electromyography procedures if performed
G. Support of the clinical effectiveness of the injections
H. A complete description of the site(s) injected

III. CRITERIA FOR APPROVAL

A. Authorization of 6 months may be granted for the requested medication when all of the following are met:
   1. The patient is not currently receiving botulinum toxin treatment.
   2. The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57186]).
   3. 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.
   4. 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
   5. If the patient has any of the following indications, they must meet the associated criteria:
      i. For Duane's Syndrome, the requested medication will be used for medial rectus weakness only
      ii. 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
      iii. 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
      iv. For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
      v. 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.

B. Authorization of 6 months may be granted for the requested medication when all of the following are met:
   1. The patient is currently receiving botulinum toxin treatment and has experienced a positive response.
   2. The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57186]).
   3. 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.
   4. 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
   5. If the patient has any of the following indications, they must meet the associated criteria:
      i. For Duane's Syndrome, the requested medication will be used for medial rectus weakness only
      ii. 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
      iii. 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
   iv. For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
   v. 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.

C. Authorization of 1 month may be granted for the requested medication when all of the following are met:
   1. The patient is currently receiving botulinum toxin treatment and has not experienced a positive response.
   2. 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.
   3. The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57186]).
   4. 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.
   5. 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
   6. If the patient has any of the following indications, they must meet the associated criteria:
      i. For Duane's Syndrome, the requested medication will be used for medial rectus weakness only
      ii. 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
      iii. 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
      iv. For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
      v. 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.

D. Authorization of 1 month may be granted for the requested medication when all of the following are met:
   1. The patient is currently receiving botulinum toxin treatment and has not experienced a positive response.
   2. The patient is receiving the maximum dose which could be utilized for the size of the muscle being treated.
   3. An alternate botulinum toxin is being requested.
   4. The patient has an ICD-10 code specified in the Local Coverage Article (Billing and Coding: Botulinum Toxin Types A and B [A57186]).
   5. 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.
   6. 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
   7. If the patient has any of the following indications, they must meet the associated criteria:
      i. For Duane's Syndrome, the requested medication will be used for medial rectus weakness only
      ii. 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

iii. 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
iv. For migraine headaches, the patient experiences at least 15 headache days per month with each headache lasting at least 4 hours
v. 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.

IV. REFERENCES

1. Botulinum Toxins LCD (L35172) Version R16. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 5, 2022.
2. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57186) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 5, 2022.