Reference number(s)
4825-A

JURISDICTION SPECIFIC MEDICARE PART B

BOTULINUM TOXINS
BOTOX (onabotulinumtoxinA)
DYSPORT (abobotulinumtoxinA)
XEOMIN (incobotulinumtoxinA)
MYOBLOC (rimabotulinumtoxinB)

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 ICD-10-CM codes is prohibitively long to include within this policy. A complete list can be found in Billing and Coding document for Botulinum Toxin Type A & Type B (A57474) at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Spasticity (including blepharospasm, dystonia and hemifacial spasm)
B. Chronic migraine headache
C. Achalasia
D. Anal fissure
E. Hyperhidrosis
F. Sialorrhea
G. Urinary incontinence
H. Neurogenic detrusor overactivity and urinary incontinence
I. Strabismus
J. Voice and speech disturbances

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 and valid and documented reasons stating why the requested product is being requested for such indication.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Documentation of a covered diagnosis
B. Documentation supporting medical necessity of the botulinum toxin (type A or type B) injection

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C. For electromyography procedures: Documentation supporting medical necessity of electromyography procedures performed in conjunction with botulinum toxin type A injections to determine the proper injection site(s)
D. For chronic migraine: Medical Record supporting the treatment of chronic migraine with a history of 15 or more headache days per month, eight of which have migraine features.
E. Dosage and frequency of the injections
F. Support of the clinical effectiveness of the injections
G. Specific site(s) injected

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. Use of botulinum toxin for the treatment of irritable colon, biliary dyskinesia, headaches, craniofacial wrinkles or any treatment of other spastic conditions not listed as covered in this policy (including the treatment of smooth muscle spasm)
B. Use of botulinum toxin for patients receiving aminoglycosides, which may interfere with neuromuscular transmission
C. Use of botulinum toxin for patients with chronic paralytic strabismus, except to reduce antagonistic contractor in conjunction with surgical repair
D. Use of botulinum toxin treatments where the goal is to improve appearance rather than function
E. Treatment exceeding accepted dosage parameters unless supported by individual medical record review
F. Not billing the corresponding surgery code when botulinum toxin is used before or after surgery

IV. CRITERIA FOR APPROVAL

A. Spastic conditions

Authorization of 6 months may be granted for treatment of lower limb spasticity, upper limb spasticity, cervical dystonia (spasmodic torticollis), blepharospasm, or hemifacial spasm when all of the following criteria are met:
1. The requested product is FDA-approved for the intended use, OR there is a valid and documented reason to use another product.
2. Prescriber agrees to discontinue treatment when there is no response after a maximum dose per injection site and the muscle group has been reached.
3. The requested botulinum toxin product will be given no more frequently than every 90 days.

Authorization of 6 months may be granted for treatment of other spastic conditions when all of the following criteria are met:
1. Prescriber agrees to discontinue treatment when there is no response after a maximum dose per injection site and the muscle group has been reached.
2. The requested botulinum toxin product will be given no more frequently than every 90 days.

B. Chronic migraine prophylaxis

Authorization of 6 months may be granted for the treatment of chronic migraine headaches when both of the following criteria are met:
1. The requested product is FDA-approved for the intended use, OR there is a valid and documented reason to use another product.

2. The requested botulinum toxin product will be given no more frequently than every 12 weeks as multiple injections around the head.
3. Member experiences headaches on 15 days or more each month for more than three months, which on at least eight days per month has the features of migraine headache.
4. Member must meet the diagnostic criteria for EITHER migraine with aura and/or migraine without aura.
    a. For migraine with aura, at least two attacks fulfilling criteria i. and ii. below:
        i. One or more of the following fully reversible aura symptoms
            1. Visual (aura, changes in vision)
            2. Sensory (e.g., tingling in hands or face, pins and needles, numbness)
            3. Speech and/or language difficulties
            4. Motor (e.g., weakness)
            5. Brainstem (e.g., vertigo, tinnitus, loss of hearing, diplopia, ataxia not attributable to sensory deficit, and decreased level of consciousness)
            6. Retinal (visual disturbance, flash of light, blind spot)
        ii. At least three of the following six characteristics
            1. At least one aura symptom spreads gradually over more than five minutes
            2. Two or more aura symptoms occur in succession
            3. Each individual aura symptoms last five to 60 minutes
            4. At least one aura symptom is unilateral
            5. At least one aura symptom is positive
            6. The aura is accompanied, or followed within 60 minutes, by headache
    b. For migraine without aura, at least five attacks fulfill the following criteria
        i. Headache attacks lasting four to 72 hours (when treated or unsuccessfully treated)
        ii. Headache has at least two of the following
            1. Unilateral location
            2. Pulsating quality
            3. Moderate or severe pain intensity
            4. Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)
        iii. During headache at least one of the following occurs:
            1. Nausea and/or vomiting
            2. Photophobia and phonophobia

C. Achalasia

Authorization of 6 months may be granted for treatment of achalasia when all of the following criteria are met:

1. The requested product is FDA-approved for the intended use, OR there is a valid and documented reason to use another product.
2. The requested product will be used in a member unfit for surgery or as a bridge to more definitive therapies such as surgery or balloon dilation.
3. Prescriber agrees to reassess the need for continued treatment if two treatments in a row fail.

D. Chronic anal fissure

Authorization of 6 months may be granted for treatment of chronic anal fissure when the member has not responded satisfactorily to conservative treatment (e.g., bulking agents, sitz baths, topical agents).

E. Overactive bladder with urinary incontinence

Authorization of 6 months may be granted for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency when all of the following criteria are met:

1. The requested product is FDA-approved for the intended use, OR there is a valid and documented reason to use another product.
2. Prescriber agrees to discontinue treatment when there is no response after a maximum dose per injection site and the muscle group has been reached.
3. The requested botulinum toxin product will be given no more frequently than every 90 days.

F. Detrusor overactivity associated with a neurologic condition

Authorization of 6 months may be granted for the treatment of urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) when all of the following criteria are met:

1. The requested product is FDA-approved for the intended use, OR there is a valid and documented reason to use another product.
2. Prescriber agrees to discontinue treatment when there is no response after a maximum dose per injection site and the muscle group has been reached.
3. The requested botulinum toxin product will be given no more frequently than every 90 days.

G. Sialorrhea (excessive salivation)

Authorization of 6 months may be granted for sialorrhea (excessive salivation).

H. Hyperhidrosis (excessive sweating)

Authorization of 6 months may be granted for treatment of primary focal hyperhidrosis of the axilla, face, palms and/or soles when all of the following are met:

1. The requested product is FDA-approved for the intended use, OR there is a valid and documented reason to use another product.
2. The condition significantly affects the member's quality of life.
3. The condition is inadequately managed with topical agents.

I. Strabismus

Authorization of 6 months may be granted for the treatment of strabismus when the requested product is FDA-approved for the intended use, OR there is a valid and documented reason to use another product.

J. Voice and speech disturbances

Authorization of 6 months may be granted for the treatment of voice and speech disturbances.

V. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV and under "ICD-10-CM Codes that Support Medical Necessity" of article A57474 unless any two treatments in a row, utilizing an appropriate or maximum dose of botulinum toxin failed to produce satisfactory clinical response.

VI. DOSAGE AND ADMINISTRATION

Treatment may not exceed accepted dosage parameters.

VII. REFERENCES

Reference number(s)
4825-A

1. Botulinum Toxin Type A and Type B LCD (L34635) Version R12. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 10, 2022.
2. Billing and Coding: Botulinum Toxin Type A & Type B (A57474) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 10, 2022.
3. Botox [package insert]. Irvine, CA: Allergan, Inc.; July 2021.
4. Dysport [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; July 2020.
5. Xeomin [package insert]. Dessau-Rosslau, Germany: Merz Pharmaceuticals, LLC. August 2021.
6. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.