

Policy Name:	Botulinum Toxin (BTX) Treatment for Non-Cosmetic Indications
Effective Date:	10/1/2020

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Botulinum toxin (BTX) products are COVERED for non-cosmetic indications including but not limited to:

1. Dystonias or spasmodic torticollis (cervical dystonia)
2. Blepharospasm, strabismus, or esotropia
3. Upper limb, lower limb or other spastic conditions that are unresponsive to other treatments
4. Prophylaxis of chronic migraines in adult patients when first-line prophylactic agents (e.g. beta-blockers, tricyclic antidepressants and antiepileptic drugs) have failed or are contraindicated AND when not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g. eptinezumab, erenumab, galcanezumab, fremanezumab, etc.)
5. Severe axillary or palmar hyperhidrosis in patients who have medical complications, such as secondary infection, or who have significant functional impairment and have documented failure of topical treatment
6. Urinary incontinence due to detrusor over activity associated with a neurologic condition OR overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency when response to anticholinergic agents (e.g. darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) is inadequate or treatment with anticholinergic agents is contraindicated
7. Chronic sialorrhea associated with neurological disorders
8. Esophageal achalasia when patient has a high risk or history of complication or treatment failure from pneumatic dilation or surgical myotomy
9. Chronic anal fissure after failure of non-pharmacologic supportive measures (i.e., sitz baths, psyllium fiber, bulking agents, etc.) AND a ≥ 1 month trial of conventional pharmacologic therapy (e.g. oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanecol, etc.)
10. Ventral hernia

Cosmetic procedures are excluded from coverage. Any use of BTX for cosmetic indications is NOT COVERED.

Note: This policy is no longer scheduled for routine review of the scientific literature.

Description

Botulinum toxin products are produced using a biologic neurotoxin produced by the bacterium, *Clostridium botulinum*. Commercially-purified Botulinum toxin products have been investigated as therapeutic injectable agents. When injected into a muscle, Botulinum toxin binds to nerve endings at the location where the nerves join muscles and prevent the nerves from signaling the muscles to contract. The injections paralyze muscles temporarily, resulting in relief of the symptoms associated with some types of excessive muscle contractions or neurological disorders involving muscle posture and tension. Botulinum toxin is not a curative treatment. Its effects are dose dependent and last for approximately two to six months.

FDA Approval

Onabotulinumtoxin A (Botox®, Allergan, Inc.) is FDA-approved for the prophylaxis of headaches in adults with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer), treatment of upper limb or lower limb spasticity in children ≥ 2 years of age and adults, treatment of cervical dystonia in adults, treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adults, treatment of blepharospasm associated with dystonia in patients ≥ 12 years of age, treatment of strabismus in patients ≥ 12 years of age, and treatment of urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g. spinal cord injury, multiple sclerosis) and overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.

Abobotulinumtoxin A (Dysport®, IPSEN) is FDA approved in the treatment of upper and lower limb spasticity in adults and pediatric patients 2 years or older and the treatment of cervical dystonia in adults.

Rimabotulinumtoxin B (Myobloc®, Solstice Neurosciences, Inc) is FDA approved for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia and treatment of chronic sialorrhea in adults.

Incobotulinumtoxin A (Xeomin®, Merz Pharmaceuticals, LLC) is FDA approved for treatment of adults with cervical dystonia, treatment of upper limb spasticity in adults, treatment of upper limb spasticity (excluding spasticity caused by cerebral palsy) in pediatrics, treatment of chronic sialorrhea in adults, and the treatment of blepharospasm in adults.

Note: These products are distinct and their dosing units are not interchangeable with other botulinum toxin agents. The dosing units of each product cannot be compared to, nor converted from one product to any other botulinum toxin product.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement. (denial)

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met. (split)

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member

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coverage or provider reimbursement.

CPT Codes

Use the current applicable CPT/HCPCS code(s).

Onabotulinumtoxin A (Botox®) – J0585, 1 unit

Abobotulinumtoxin A (Dysport®) – J0586, 5 units

Rimabotulinumtoxin B (Myobloc®) – J0587, 100 units

Incobotulinumtoxin A (Xeomin®) – J0588, 1 unit

Original Effective Date: 12/16/2004

Re-Review Date(s): 09/22/2020, 9/27/2016, 10/30/2014, 5/7/2013, 9/15/2011, 4/21/2011, 5/21/2008, 12/16/2004

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