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**Dean Health Plan Medical Policy:**

OnabotulinumtoxinA, IncobotulinumtoxinA, RimabotulinumtoxinB and AbobotulinumtoxinA require prior authorization through the Quality and Care Management Division and is considered medically necessary for members who meet the following criteria for the listed indications.

**IncobotulinumtoxinA (XEOMIN) (J0588)** may be indicated for the following:

1.0 Cervical dystonia (spasmodic torticollis) in patients 16 years of age or older when all of the following criteria are met:
   1.1 No infection at proposed injection site; and
   1.2 Neck pain or abnormal head position causing adverse effect on daily functioning; and
   1.3 No fixed contractures causing decreased neck range of motion; and
   1.4 No neuromuscular disease (eg, myasthenia gravis).

2.0 Blepharospasm for patients age 18 or older, as indicated by ALL of the following:
   2.1 Diagnosis of benign essential blepharospasm
   2.2 No neuromuscular disease
   2.3 No infection at proposed injection site
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3.0 Upper Limb Spasticity in adults due to stroke

**RimabotulinumtoxinB (MYOBLOC) (J0587)** may be indicated for the following:

4.0 Cervical dystonia (spasmodic torticollis) in patients 16 years of age or older when all of the following criteria are met:
   - 4.1 No infection at proposed injection site; and
   - 4.2 Neck pain or abnormal head position causing adverse effect on daily functioning; and
   - 4.3 No fixed contractures causing decreased neck range of motion; and
   - 4.4 No neuromuscular disease (eg, myasthenia gravis).

5.0 Sialorrhea (excessive salivation) due to neurologic disease

**AbobotulinumtoxinA (DYSPORT) (J0586)** may be indicated for the following:

6.0 Blepharospasm for patients age 18 or older, as indicated by ALL of the following:
   - 6.1 Diagnosis of benign essential blepharospasm
   - 6.2 No neuromuscular disease
   - 6.3 No infection at proposed injection site

7.0 Cervical dystonia (spasmodic torticollis) in patients 16 years of age or older when all of the following criteria are met:
   - 7.1 No prior surgical treatment; and
   - 7.2 No infection at proposed injection site; and
   - 7.3 Neck pain or abnormal head position causing adverse effect on daily functioning; and
   - 7.4 No fixed contractures causing decreased neck range of motion; and
   - 7.5 No neuromuscular disease (eg, myasthenia gravis).

8.0 Hemifacial spasm

9.0 Hyperhidrosis (axillary) in patients 18 years of age or older when all of the following criteria are met:
   - 9.1 Significant effect of hyperhidrosis on daily activities; and
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9.2 Conservative treatment, including topical agents, have failed; and
9.3 Secondary causes of hyperhidrosis (eg, hyperthyroidism) have been evaluated and, if necessary, treated.
9.4 No infection at proposed injection site.
9.5 Axillary hyperhidrosis, with resting sweat production of 50 mg per axilla measured over 5 minutes at room temperature.

10.0 Sialorrhea (excessive salivation)
11.0 Spasticity, as indicated by 1 or more of the following:
   11.1 Child with cerebral palsy receiving rehabilitation; or
   11.2 Upper extremity spasticity in adult due to stroke
12.0 Upper extremity dystonia (eg, writer's cramp), for patient's age 16 years or older, as indicated by ALL of the following:
   12.1 Extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning; and
   12.2 No prior surgical treatment; and
   12.3 No infection at proposed injection site

**OnabotulinumtoxinA (BOTOX) (J0585)** may be indicated for one (1) or more of the following:

13.0 Achalasia when **all** of the following criteria are met:
   13.1 Progressive dysphagia for liquids and solids; and
   13.2 Diagnosis of achalasia confirmed by esophageal manometry; and
   13.3 Other causes of dysphagia ruled out by upper gastrointestinal endoscopy; and
   13.4 Pharmacological treatment has failed.

14.0 Anal fissure when **all** of the following criteria are met:
   14.1 At least 2 months of symptoms including one of the following: nocturnal pain and bleeding OR post-defecation pain; and
   14.2 No inflammatory bowel disease; and
   14.3 No hemorrhoids; and
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14.4 No HIV disease; and
14.5 No anal fistula; and
14.6 No perianal abscess, cancer or previous surgery; and
14.7 Failure or intolerance of topical nitrates; and
14.8 Patient is not a surgical candidate

15.0 Blepharospasm in patients 12 years of age or older who have blepharospasm associated with no neuromuscular disease (eg, myasthenia gravis) and at least one of the following:
   15.1 Dystonia; or
   15.2 Facial nerve disorders (e.g. Bell Palsy); or
   15.3 Benign essential blepharospasm.

16.0 Cervical dystonia (spasmodic torticollis) in patients 16 years of age or older when all of the following criteria are met:
   16.1 No infection at proposed injection site; and
   16.2 Neck pain or abnormal head position causing adverse effect on daily functioning; and
   16.3 No fixed contractures causing decreased neck range of motion; and
   16.4 No neuromuscular disease (eg, myasthenia gravis).

17.0 Hemifacial spasm

18.0 Hyperhidrosis (axillary) in patients 18 years of age or older when all of the following criteria are met:
   18.1 Significant effect of hyperhidrosis on daily activities; and
   18.2 Conservative treatment, including topical agents, have failed; and
   18.3 Secondary causes of hyperhidrosis (eg, hyperthyroidism) have been evaluated and, if necessary, treated.
   18.4 No infection at proposed injection site.
   18.5 Axillary hyperhidrosis, with resting sweat production of 50 mg per axilla measured over 5 minutes at room temperature.

19.0 Migraine headache prophylaxis needed for those 18 years or older, as indicated by all of the following:
   19.1 Migraine headache, as indicated by 5 or more attacks with ALL of the following:
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19.1.1 Headache symptoms, as indicated by 2 or more of the following:
   19.1.1.1 Aggravation by or causing avoidance of routine physical activity
   19.1.1.2 Moderate or severe pain intensity
   19.1.1.3 Pulsating quality
   19.1.1.4 Unilateral location

19.2 Migraine associated symptoms, as indicated by either nausea/vomiting, or Photophobia and phonophobia.

19.3 Migraine headache frequency occurring 15 or more days per month for 3 or more months

19.4 No medication-overuse headaches

19.5 No neuromuscular disease (eg, myasthenia gravis)

19.6 Other therapeutic options have been ineffective or not tolerated for trial of at least 3 months, as indicated by 1 or more of the following:
   19.6.1 Use of ergotamine, triptans, or combination analgesics for 10 or more days per month or
   19.6.2 Use of simple analgesics or any combination of ergotamine, triptans, analgesics, and opioids for 15 or more days per month

19.7 Have tried and failed trials of at least 3 medications selected from at least two classes of migraine headache prophylaxis medications of at least 2 months duration for each medication:
   19.7.1 Beta blockers (e.g., propranolol, atenolol)
   19.7.2 Anti-depressants (e.g., amitriptyline)
   19.7.3 Anti-epileptics (e.g., gabapentin, topiramate)
   19.7.4 Calcium channel blockers (e.g., verapamil)
   19.7.5 Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (e.g., Lisinopril, losartan)

19.8 Continuing treatment with botulinum toxin injection for ongoing prevention of chronic migraine headaches is considered medically necessary when there is documentation that migraine headache frequency was reduced or duration was reduced.
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20.0 Motor tics in patients 16 years of age or older when all of the following criteria are met:

- 20.1 The tics cause interference with daily living; and
- 20.2 Patient unable to adequately suppress tics; and
- 20.3 Failure of trials of several different neuroleptic drugs (e.g. haloperidol).

21.0 Neurogenic urinary incontinence, neurogenic detrusor overactivity or detrusor sphincter dyssynergia when all of the following criteria are met:

- 21.1 The condition is secondary to a spinal cord injury or neurologic disease (e.g., multiple sclerosis); and
- 21.2 Surgical treatment or balloon sphincter dilatation is not indicated or has failed; and
- 21.3 Pharmacologic therapy has failed; and
- 21.4 No acute urinary retention unless patient receiving regular clean intermittent catheterization; and
- 21.5 Age 18 years or older.

22.0 Overactive bladder with urge urinary incontinence, as indicated by all of the following:

- 22.1 Age 18 years or older; and
- 22.2 Failure of or intolerance to anticholinergic medication; and
- 22.3 No acute urinary retention; and
- 22.4 No acute urinary tract infection; and
- 22.5 Urge urinary incontinence demonstrated on urodynamic testing

23.0 Sialorrhea (excessive salivation)

24.0 Spasticity, as indicated by 1 or more of the following:

- 24.1 Child with cerebral palsy receiving rehabilitation; or
- 24.2 Hereditary spastic paraplegia; or
- 24.3 Limb spasticity due to multiple sclerosis or other demyelinating diseases of the central nervous system
- 24.4 Spastic hemiplegia, such as due to stroke or brain injury
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25.0 Strabismus in patients 12 years of age or older when all of the following criteria are met:
   25.1 Deviation of 50 prism diopters or less; and
   25.2 No infection at proposed injection site; and
   25.3 Strabismus not due primarily to restrictive strabismus, Duane syndrome with lateral rectus weakness, or caused by prior surgical over-recession of antagonist muscle.

26.0 Upper extremity dystonia (eg, writer's cramp), for patient's age 16 years or older, as indicated by all of the following:
   26.1 Extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning; and
   26.2 No prior surgical treatment; and
   26.3 No infection at proposed injection site

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**Committee/Source**

**Originated:** Utilization Management Committee/Blue Cross/Blue Shield, Technologica, 9/96, The Executive Summary File, Vol. 11, No. 6, 1996

**Revised:**
- Utilization Management Committee/ Medical Affairs Technology Review
- Utilization Management Committee/ Dean GI Dept.
- Utilization Management Committee/ Customer Service
- Utilization Management Committee Medicare 9/2001/HAYES 7/2001
- Utilization Management Committee/ Medical Affairs/ Medicare Part B, 3/2002
- Utilization Management Committee/ Referral Dept.
- Utilization Management Committee/Medical Affairs
- Utilization Management Committee/Medical Affairs
- Utilization Management Committee/Medical Affairs
- Medical Director Committee/Medical Affairs
- Medical Director Committee/Medical Affairs
- Medical Director Committee/Medical Affairs
- Medical Director Committee/Medical Affairs

**Date(s)**
- February 19, 1997
- September 9, 1999
- January 19, 2000
- February 14, 2001
- October 10, 2001
- May 8, 2002
- July 10, 2002
- February 11, 2004
- January 14, 2009
- June 10, 2009
- June 16, 2010
- November 18, 2010
- June 23, 2011
- September, 19, 2012
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