Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 12/12/2024

Botulinum Toxin Type B Injection

Myobloc® (rimabotulinumtoxinB)

HCPCS: J0587

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. A confirmed diagnosis of cervical dystonia or spasmodic torticollis with documentation of involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures. Documentation of functional impairment from cervical dystonia or spasmodic torticollis will be required.
   OR
   b. Chronic sialorrhea (excessive saliva) in adults.
   c. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents.
   d. Botulinum toxin type B is not covered for skin wrinkles or other cosmetic indications
   e. Botulinum toxin type B is considered investigational when used for all other conditions, including but not limited to:
      i. Axillary hyperhidrosis
      ii. Carpal tunnel syndrome
      iii. Cerebral palsy
      iv. Palmar hyperhidrosis
      v. Refractory detrusor overactivity
      vi. Spasmodic dystonia
      vii. Spastic movement disorders in children
      viii. Upper limb spasticity following stroke

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period:
      i. Initial: 6 months
      ii. Renewal: Annually
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- There are four botulinum neurotoxins marketed in the United States; 3 types A and 1 type B brands.

- Botulinum neurotoxins are produced by different biological manufacturing processes, obtained by different isolation and purification techniques and derived from different *Clostridium* batches.

- FDA labeling indicates that units of rimabotulinumtoxinB cannot be compared to or converted into units of any other botulinum toxin. Therefore, the efficacy, dosing and safety of rimabotulinumtoxinB cannot be based on extrapolation from other studies using other botulinum toxin serotypes.

- Use of botulinum toxin (all serotypes) for treatment of wrinkles or other cosmetic conditions is considered not medically necessary.

- Results from three clinical studies support the efficacy of rimabotulinumtoxinB in reducing neck pain and the severity of the abnormal head position associated with cervical dystonia or spasmodic torticollis in patients previously responsive to BTX-A or those patients who no longer respond to BTX-A.

    - Cervical dystonia (or spasmodic torticollis) is characterized by involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures.

- Anatomically guided injections of rimabotulinumtoxinB into the parotid and submandibular glands appear to effectively improve sialorrhea without causing dysphagia in patients with Parkinson's disease. A small trial in 20 subjects demonstrated a similar effect in patients with amyotrophic lateral sclerosis (ALS). A small trial in 26 subjects demonstrated a decrease in frequency and severity of sialorrhea in children with cerebral palsy who received a 3,000 MU injection of rimabotulinumtoxinB into the salivary glands.

- Use of botulinum toxic type B in other conditions

    - There are four pilot studies of 20 subjects each that investigate rimabotulinumtoxinB for use in palmer hyperhidrosis, axillary hyperhidrosis, refractory detrusor overactivity, and carpal tunnel syndrome. The evidence from these trials is of poor quality. Larger, well-designed trials are necessary to confirm the results.

    - Additional pilot studies, case reports and observational studies have suggested potential benefit of rimabotulinumtoxinB in the treatment of spasmodic dystonia, axillary hyperhidrosis, upper limb spasticity following stroke, spastic movement disorders in children and arm dystonia in children with cerebral palsy. The evidence from these trials is of poor quality. Larger, well-designed clinical trials are needed to assess safety and efficacy of rimabotulinumtoxinB in these conditions.

References:

1. LewMF et al. Botulinum toxin type B: a double-blind, placebo-controlled, safety and efficacy study in cervical dystonia. Neurology 1997;49:701-7.
2. ComellaCL et al. Teaching tape for the motor section of the Toronto Western Spasmodic TorticollisScale. MovDisord 1997;12(4):570-5.
3. Brashear A et al. Safety and efficacy of NeuroBloc (botulinumtoxin type B) in type A-responsive cervical dystonia. Neurology 1999;53:1439-46.
4. Brin MF et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-resistant cervical dystonia. Neurology 1999;53:1431-8.
5. Baumann L et al. A double-blinded, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc® (botulinum toxin type B)-purified neurotoxin complex for the treatment of crow's feet: a double-blinded, placebo-controlled trial. DermatolSurg2003;29(5):508-15.
6. OndoWG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. Neurology 2004;62(1):37-40.
7. Myobloc® (botulinum toxin type B) [package insert]. Solstice Neurosciences, Inc., South San Francisco, CA. August 2009.
8. Baumann L, et al. Double-blind, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for the treatment of palmar hyperhidrosis. Dermatol Surg. 2005;31(3):263-70.
9. Baumann L, et al. Pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for treatment of axillary hyperhidrosis. Int J Dermatol. 2005;44(5):418-24.
10. Ghei M, et al. Effects of botulinum toxin B on refractory detrusor overactivity: a randomized, double-blind, placebo controlled, crossover trial. J Urol. 2005;174:1873-7.
11. Breuer B, Sperber K, Wallenstein S, et al. Clinically significant placebo analgesic response in a pilot trial of botulinum B in patients with hand pain and carpal tunnel syndrome. Pain Medicine 2006;7:16-24.
12. Botulinum Toxin Types A and B, Medicare Medical Policy, B2002.20R1; 5/2006.
13. Hirst GR et al. Botulinum toxin B is not an effective treatment of refractory overactive bladder. Urology 2007;69:69-73.
14. Sataloff RT et al. Botulinum toxin type B for the treatment of spasmodic dysphonia: a case report. Journal of Voice 2002; 16(3):422-24.
15. Dressler D et al. Botulinum toxin type B for treatment of axillary hyperhidrosis. J Neurol 2002; 249:1729-32.
16. Brashear A et al. Treatment with botulinum toxin type B for upper limb spasticity. Arch Phys Med Rehabil 2003;84:103-07.
17. Lagalla G, Millevolte M, Capecci M, Provinciali L, Ceravolo MG. Long-lasting benefits of botulinum toxin type B in Parkinson's disease-related drooling. J Neurol. 2009 Apr;256(4):563-7. Epub 2009 Apr 23.
18. Jackson CE, Gronseth G, Rosenfeld J, Barohn RJ, Dubinsky R, et al.; Muscle Study Group. Randomized double-blind study of botulinum toxin type B for sialorrhea in ALS patients. Muscle Nerve. 2009;39(2):137-43.
19. Schwerin A et al. Botulinum toxin B treatment in children with spastic movement disorders: a pilot study. Pediatric Neurology 2003; 31:109-13.
20. Sanger TD et al. Botulinum toxin type B improves the speed Journal of Child Neurology 2007; 22(1):116-22.
21. Hauser SL, Josephson SA, Harrison TR, Kasper DL, English JD, Braunwald E, Fauci AS, Engstrom JW, Longo DL, editors. Harrison's Neurology in Clinical Medicine. 16th ed. New York: McGraw-Hill Professional; 2006.
22. Basciani M, Di Rienzo F, Fontana A, Copetti M, Pellegrini F, Intiso D. Botulinum toxin type B for sialorrhea in children with cerebral palsy: a randomized trial comparing three doses. Dev Med Child Neurol. 2011 Jun;53(6):559-64.
23. Albanese A. Terminology for preparations of botulinum neurotoxins: what a difference a name makes. JAMA. 2012;305:89-90.
24. Myobloc® (rimabotulinumtoxinB) [package insert]. Solstice Neurosciences, LLC., Louisville, KY. August 2019.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.6</td><td>Effective Date: 12/12/2024</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.5</td><td>Effective Date: 12/14/2023</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.4</td><td>Effective Date: 12/01/2022</td><td>Updated to include trial and failure of preferred products statement</td></tr>
<tr><td>2.3</td><td>Effective Date: 10/06/2022</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.2</td><td>Effective Date: 10/07/2021</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.1</td><td>Effective Date; 10/08/2020</td><td>Annual Review</td></tr>
<tr><td>2.0</td><td>Effective Date: 11/7/2019</td><td>Update new indication for chronic sialorrhea</td></tr>
<tr><td>1.9</td><td>Effective Date: 05/08/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.8</td><td>Effective Date: 05/03/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.7</td><td>Effective Date: 07/05/2017</td><td>UM medical management system update for BCNA and MAPPO
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.6</td><td>Effective Date: 05/04/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.5</td><td>Effective Date: 12/01/2016</td><td>UM medical management system update for BCN
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.4</td><td>Effective Date: 02/11/2016</td><td>Updated criteria for cervical dystonia and spasmodic torticollis to include functional impairment as a requirement</td></tr>
<tr><td>1.3</td><td>Effective Date: 02/12/2015</td><td>Updated time frames (initial 6 months, continuation 1 year). This was due to a letter written from Dr Saper.</td></tr>
<tr><td>1.2</td><td>Effective Date: 05/02/2013</td><td>Updated criteria, extended authorization period</td></tr>
</table>

<table>
<tr><td>1.1</td><td>Effective Date:
01/22/2013</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effective Date:
11/08/2012</td><td>New Policy –separated from Botulinum Toxin A
- Custom/clinical formulary: N/A
- Part D: Specialty B vs D
- Part D Formulary Chapter: Central Nervous System: Miscellaneous CNS
- Recommended criteria and QL</td></tr>
</table>

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form

Botox® (onabotulinumtoxinA) J0585 **Dysport™ (abobotulinumtoxinA) J0586**
Xeomin® (incobotulinumtoxinA) J0588 **Myobloc® (rimabotulinumtoxinB) J0587**
Daxxify® (abobotulinumtoxinA) C9160

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

This form is to be used by participating physicians to obtain coverage for botulinum products. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Initial or Continuation request? ☐ Initial ☐ Continuation *Date patient started therapy:* _____

2. Please provide the NPI number for the place of administration: _____

3. **Initiation AND Continuation of therapy:**
   a. **What diagnosis is Botulinum Toxin Type B (Myobloc) being used for?**
      ☐ Chronic sialorrhea
      ☐ Cervical dystonia (spasmodic torticollis)
      ☐ Other: _____

   b. **What diagnosis is Botulinum Toxin Type A (Botox/Dysport/Xeomin) being used for:**
      ☐ Anal Fissure
      ☐ Achalasia/cardiospasm
      ☐ Primary axillary hyperhidrosis
      ☐ Gustatory or palmer hyperhidrosis
      ☐ Headache (go to g)
      ☐ Urinary incontinence
      ☐ Chronic sialorrhea
      ☐ Pelvic floor spasms
      ☐ Spasticity or dystonia (go to j)
      ☐ Cosmetic use
      ☐ Other: _____

   c. **Anal Fissure:** Has the patient experienced treatment failure with nitroglycerin ointment or diltiazem cream? ☐ Yes ☐ No Explain _____

   d. **Achalasia/cardiospasm:**
      i. Has the patient responded to dilation therapy for this condition? ☐ Yes ☐ No ☐ Member has not received dilation therapy
      ii. Is the patient a candidate for surgery? ☐ Yes ☐ No

   e. **Primary axillary hyperhidrosis:**
      i. What factors have contributed to the patient's hyperhidrosis?
         ☐ Another diagnosis (ex: hyperthyroidism or anxiety): _____
         ☐ Another drug (ex: opioids or antidepressants): _____
         ☐ No other factors contribute to patient's hyperhidrosis
         ☐ Other factors: _____
      ii. Has the patient tried and failed topical antiperspirants and/or anticholinergic medications (ex: glycopyrrolate or oxybutynin)? ☐ Yes ☐ No Explain _____
      iii. Has the member's diagnosis resulted in medical complications (ex: skin maceration with secondary infection)? ☐ Yes ☐ No Explain _____

   f. **Gustatory or palmer hyperhidrosis:** Has this resulted in medical complications (ex: skin maceration with secondary infection)? ☐ Yes ☐ No Explain: _____

   g. **Headache:**
      i. What type of headache does the patient have? ☐ Tension ☐ Cluster ☐ Medication overuse ☐ Chronic migraine headache ☐ Other: _____
      ii. What is the frequency of chronic migraine headache days (before/after starting botulinum toxins) as documented by the patient's headache diary or calendar?
         PRIOR TO botulinum toxin: _____ days/month AND _____ hours/month
         AFTER botulinum toxin: _____ days/month AND_____hrs/month
      iii. What long term daily preventative treatments has the patient tried and failed for at least 6 weeks?
         ☐ Anticonvulsants (Must be: topiramate, sodium valproate, divalproex, or carbamazepine): _____
         ☐ ACE inhibitor/ARB: _____
         ☐ B-blockers: _____
         ☐ Calcium Channel Blockers: _____
         ☐ Antidepressants (Must be amitriptyline or venlafaxine): _____
         ☐ Triptans: _____
         ☐ Calcitonin gene-related peptide (CGRP): _____
         ☐ Other: _____

12/18/2015;10/11/2018; 6/26/2019; 3/17/2020; 4/8/2021; 10/6/2022, 12/14/2023

h. **Urinary incontinence:**

i. What is the cause of the incontinence?

☐ Detrusor overactivity associated with a neurogenic condition ☐ Idiopathic detrusor overactivity ☐ Overactive bladder ☐ Other: _____

ii. What other medications has the patient experienced treatment failure with for the diagnosis?

☐ Ditropan ☐ Detrol ☐ Enablex ☐ Toviaz ☐ Sanctura ☐ Mirabegron (Myrbetriq) ☐ Other: _____

i. **Pelvic floor spasms:** Which therapies has the patient experienced treatment failure with for the diagnosis of pelvic floor spasms?

☐ Muscle relaxants (for example: Baclofen) ☐ Benzodiazepines (for example: Diazepam) ☐ Other: _____

j. **Spasticity or dystonia:**

i. Which of the following conditions is the spasticity or dystonia associated with?

☐ Blepharospasm
☐ Central demyelinating of corpus callosum
☐ Cerebral Palsy
☐ Demyelinating diseases of CNS
☐ Facial nerve VII disorders
☐ Facial myokymia, Melkersson's syndrome, facial/hemifacial spasms
☐ Hereditary spastic paraplegia
☐ Laryngeal spasm; laryngeal adductor spastic dysphonia, or stridulous
☐ Leukodystrophy
☐ Multiple sclerosis
☐ Neuromyelitis optica
☐ Organic writer's cramp
☐ Orofacial dyskinesia (for example: jaw closure dystonia) or Meige syndrome
☐ Schilder's disease
☐ Spasmodic dysphonia
☐ Spastic hemiplegia
☐ Spasticity related to spinal cord injury or stroke
☐ Strabismus
☐ Torsion dystonia, idiopathic and symptomatic (Oppenheim's dystonia)
☐ Upper limb spasticity (elbow flexors, wrist flexors, finger flexors, thumb flexors)
☐ Lower limb spasticity (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus and flexor digitorum longus)
☐ Cervical dystonia (spasmodic torticollis)
☐ Muscle spasm
☐ Other; Please provide the condition the spasticity or dystonia is associated with:_____

ii. Please select the symptoms associated with the diagnosis of **cervical dystonia/spasmodic torticollis**?

☐ Involuntary contractions of the neck muscles ☐ Twisting/repetitive movements ☐ Abnormal postures ☐ Other: _____

iii. The patient's diagnosis resulted in: ☐ Significant functional impairment ☐ Medical complications ☐ No complications

4. **Continuation request**: (**For migraine see 3g**) ☐ Improvement in symptoms ☐ Clinically stable ☐ Worsening of symptoms ☐ No response ☐ Unknown

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	**Physician Signature**	**Date**
Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ Concurrent Medical Problems ☐ Prior Therapies
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

12/18/2015;10/11/2018; 6/26/2019; 3/17/2020; 4/8/2021; 10/6/2022, 12/14/2023