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Effective Date: 12/14/2023

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

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***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:

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Policy History												
#	Date	Change Description										
2.5	Effective Date: 12/14/2023	Annual review of criteria was performed, no changes were made										
2.4	Effective Date: 12/01/2022	Updated to include trial and failure of preferred products statement										
2.3	Effective Date: 10/06/2022	Annual review of criteria was performed, no changes were made										
2.2	Effective Date: 10/07/2021	Annual review of criteria was performed, no changes were made										
2.1	Effective Date; 10/08/2020	Annual Review										
2.0	Effective Date: 11/7/2019	Update new indication for chronic sialorrhea										
1.9	Effective Date: 05/08/2019	Annual Review of Medical Policy										
1.8	Effective Date: 05/03/2018	Annual Review of Medical Policy										
1.7	Effective Date: 07/05/2017	UM medical management system update for BCNA and MAPPO <table border="1" data-bbox="483 835 1365 1045"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.6	Effective Date: 05/04/2017	Annual Review of Medical Policy										
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1.4	Effective Date: 02/11/2016	Updated criteria for cervical dystonia and spasmodic torticollis to include functional impairment as a requirement										
1.3	Effective Date: 02/12/2015	Updated time frames (initial 6 months, continuation 1 year). This was due to a letter written from Dr Saper.										
1.2	Effective Date: 05/02/2013	Updated criteria, extended authorization period										

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1.1	Effective Date: 01/22/2013	UM medical management system update for BCBS <table border="1" data-bbox="483 201 1365 411"> <thead> <tr> <th data-bbox="483 201 963 268">Line of Business</th> <th data-bbox="963 201 1365 268">PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td data-bbox="483 268 963 302">BCBS</td> <td data-bbox="963 268 1365 302">Yes</td> </tr> <tr> <td data-bbox="483 302 963 336">BCN</td> <td data-bbox="963 302 1365 336">No</td> </tr> <tr> <td data-bbox="483 336 963 369">MAPPO</td> <td data-bbox="963 336 1365 369">No</td> </tr> <tr> <td data-bbox="483 369 963 411">BCNA</td> <td data-bbox="963 369 1365 411">No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	No	MAPPO	No	BCNA	No
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1.0	Effective Date: 11/08/2012	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										

* 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



Botox® (onabotulinumtoxinA) J0585
Xeomin® (incobotulinumtoxinA) J0588

Dysport™ (abobotulinumtoxinA) J0586
Myobloc® (rimabotulinumtoxinB) J0587

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. <input type="checkbox"/> Male <input type="checkbox"/> 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: _____

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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 <input type="checkbox"/> Form Completely Filled Out <input type="checkbox"/> Attached Chart Notes	<input type="checkbox"/> Concurrent Medical Problems <input type="checkbox"/> 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

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