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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

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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										
2.6	Effective Date: 12/12/2024	Annual review of criteria was performed, no changes were made										
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="483 907 1365 1119"> <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										
1.5	Effective Date: 12/01/2016	UM medical management system update for BCN <table border="1" data-bbox="483 1270 1365 1482"> <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>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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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="485 201 1364 411"> <thead> <tr> <th data-bbox="485 201 963 268">Line of Business</th> <th data-bbox="963 201 1364 268">PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td data-bbox="485 268 963 302">BCBS</td> <td data-bbox="963 268 1364 302">Yes</td> </tr> <tr> <td data-bbox="485 302 963 336">BCN</td> <td data-bbox="963 302 1364 336">No</td> </tr> <tr> <td data-bbox="485 336 963 369">MAPPO</td> <td data-bbox="963 336 1364 369">No</td> </tr> <tr> <td data-bbox="485 369 963 411">BCNA</td> <td data-bbox="963 369 1364 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 <ul style="list-style-type: none"> - 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>.