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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

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

\*\*\*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:<br>12/14/2023                     | Annual review of criteria was performed, no changes were made  |                  |   |      |     |     |     |       |     |      |     |
| 2.4              | Effective Date:<br>12/01/2022                     | Updated to include trial and failure of preferred products statement   |                  |   |      |     |     |     |       |     |      |     |
| 2.3              | Effective Date:<br>10/06/2022                     | Annual review of criteria was performed, no changes were made  |                  |   |      |     |     |     |       |     |      |     |
| 2.2              | Effective Date:<br>10/07/2021                     | Annual review of criteria was performed, no changes were made  |                  |   |      |     |     |     |       |     |      |     |
| 2.1              | Effective Date;<br>10/08/2020                     | Annual Review  |                  |   |      |     |     |     |       |     |      |     |
| 2.0              | Effective Date:<br>11/7/2019                      | Update new indication for chronic sialorrhea   |                  |   |      |     |     |     |       |     |      |     |
| 1.9              | Effective Date:<br>05/08/2019                     | Annual Review of Medical Policy  |                  |   |      |     |     |     |       |     |      |     |
| 1.8              | Effective Date:<br>05/03/2018                     | Annual Review of Medical Policy  |                  |   |      |     |     |     |       |     |      |     |
| 1.7              | Effective Date:<br>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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| BCN              | Yes   |  |                  |   |      |     |     |     |       |     |      |     |
| MAPPO            | Yes   |  |                  |   |      |     |     |     |       |     |      |     |
| BCNA             | Yes   |  |                  |   |      |     |     |     |       |     |      |     |
| 1.6              | Effective Date:<br>05/04/2017                     | Annual Review of Medical Policy  |                  |   |      |     |     |     |       |     |      |     |
| 1.5              | Effective Date:<br>12/01/2016                     | UM medical management system update for BCN <table border="1" data-bbox="483 1199 1365 1409"> <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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| MAPPO            | No  |  |                  |   |      |     |     |     |       |     |      |     |
| BCNA             | No  |  |                  |   |      |     |     |     |       |     |      |     |
| 1.4              | Effective Date:<br>02/11/2016                     | Updated criteria for cervical dystonia and spasmodic torticollis to include functional impairment as a requirement   |                  |   |      |     |     |     |       |     |      |     |
| 1.3              | Effective Date:<br>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:<br>05/02/2013                     | Updated criteria, extended authorization period  |                  |   |      |     |     |     |       |     |      |     |

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| 1.1              | Effective Date:<br>01/22/2013                     | UM medical management system update for BCBS <table border="1" data-bbox="483 201 1354 411"> <thead> <tr> <th data-bbox="483 201 964 268">Line of Business</th> <th data-bbox="964 201 1354 268">PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td data-bbox="483 268 964 302">BCBS</td> <td data-bbox="964 268 1354 302">Yes</td> </tr> <tr> <td data-bbox="483 302 964 336">BCN</td> <td data-bbox="964 302 1354 336">No</td> </tr> <tr> <td data-bbox="483 336 964 369">MAPPO</td> <td data-bbox="964 336 1354 369">No</td> </tr> <tr> <td data-bbox="483 369 964 411">BCNA</td> <td data-bbox="964 369 1354 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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| BCN              | No  |   |                  |   |      |     |     |    |       |    |      |    |
| MAPPO            | No  |   |                  |   |      |     |     |    |       |    |      |    |
| BCNA             | No  |   |                  |   |      |     |     |    |       |    |      |    |
| 1.0              | Effective Date:<br>11/08/2012                     | New Policy –separated from Botulinum Toxin A <ul style="list-style-type: none"> <li>- Custom/clinical formulary: N/A</li> <li>- Part D: Specialty B vs D</li> <li>- Part D Formulary Chapter: Central Nervous System: Miscellaneous CNS</li> <li>- Recommended criteria and QL</li> </ul>   |                  |   |      |     |     |    |       |    |      |    |

\* 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>.