Wellmark Advantage Health Plan

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Effective Date: 12/01/2022

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 Wellmark Advantage Health Plan's utilization management medical drug list and/or Wellmark Advantage Health Plan'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 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/UM Medical Management System Update History		
#	Date	Change Description
1.2	Effective Date: 12/01/2022	Updated to include trial and failure of preferred products statement
1.1	Effective Date: 10/06/2022	Annual review of criteria was performed, no changes were made
1.0	Effective Date: 01/01/2022	Effective date of policy

** 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.*