Botulinum Toxin Type B Injection

Myobloc® (rimabotulinumtoxinB)

FDA approval: December 11, 2000
HCPCS: J0587
Benefit: Medical

Policy/Criteria:

Note: Request must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the below criteria 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) Excessive saliva (sialorrhea) associated with Parkinson's disease, amyotrophic lateral sclerosis (ALS), or cerebral palsy.

AND

c) Continuation of therapy requires documented positive clinical response

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a) 6 months (Initial Authorization)
   b) Authorization shall be reviewed at least every year to confirm that current criteria are met and that the medication is effective.

C. Botulinum toxin type B is not covered for skin wrinkles or other cosmetic indications

D. Botulinum toxin B is considered investigational when used for all other conditions, including but not limited to:
   a) Axillary hyperhidrosis
   b) Carpal tunnel syndrome
   c) Cerebral palsy
   d) Palmar hyperhidrosis
   e) Refractory detrusor overactivity
   f) Spasmodic dystonia
   g) Spastic movement disorders in children
   h) Upper limb spasticity following stroke
Therapeutic considerations:

A. FDA approved indication / Diagnosis
   a. RimabotulinumtoxinB is used in the treatment of cervical dystonia or spasmodic torticollis to reduce the severity and pain associated with abnormal neck position.

   *Please refer to most recent prescribing information.

B. Background Information
   a. There are four botulinum neurotoxins marketed in the United States; 3 types A and 1 type B brands.
   b. Botulinum neurotoxins are produced by different biological manufacturing processes, obtained by different isolation and purification techniques and derived from different Clostridium batches.
   c. FDA labeling indicates that units of rimabotulinumtoxinB cannot be compared to or converted into units of any other botulinum toxin. [7] Therefore, the efficacy, dosing and safety of rimabotulinumtoxinB cannot be based on extrapolation from other studies using other botulinum toxin serotypes.
   d. Use of botulinum toxin (all serotypes) for treatment of wrinkles or other cosmetic conditions is considered not medically necessary.

<table>
<thead>
<tr>
<th>Cross References</th>
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<td>None</td>
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C. Efficacy

*Please refer to most recent prescribing information.

D. Medication Safety Considerations

Black Box Warning: Yes

*Please refer to most recent prescribing information.

E. Dosing and administration
   a. Dosing:
      i. Initial dose: 2500 to 5000 Units divided among affected muscles
      ii. Subsequent dosing: optimize according to patient’s individual response
      iii. Duration of effect in patients responding to Myobloc treatment has been observed in studies to be between 12 and 16 weeks at dose of 5000 to 10,000 Units
      iv. Dosing in renal impairment: No info available
      v. Dosing in hepatic impairment: No info available

*Please refer to most recent prescribing information.
F. How supplied

<table>
<thead>
<tr>
<th>Dosage Strength</th>
<th>Volume per Vial</th>
<th>Single Vial Carton</th>
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<tbody>
<tr>
<td>2500 Units</td>
<td>0.5 mL</td>
<td>NDC 10454-710-10</td>
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<tr>
<td>5000 Units</td>
<td>1.0 mL</td>
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<tr>
<td>10,000 Units</td>
<td>2.0 mL</td>
<td>NDC 10454-712-10</td>
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References:


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<th>#</th>
<th>Date</th>
<th>Change Description</th>
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<tbody>
<tr>
<td>1.0</td>
<td>Effective Date: 11/8/12</td>
<td>New Policy—separated from Botulinum Toxin A</td>
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<tr>
<td></td>
<td></td>
<td>- Custom/clinical formulary: N/A</td>
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<td></td>
<td></td>
<td>- Part D: Specialty B vs D</td>
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<tr>
<td></td>
<td></td>
<td>- Part D Formulary Chapter: Central Nervous System: Miscellaneous CNS</td>
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<tr>
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<td>- Recommended criteria and QL</td>
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<td>1.1</td>
<td>Effective Date: 5/2/13</td>
<td>Updated criteria, extended authorization period</td>
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<tr>
<td>1.2</td>
<td>Effective Date: 2/12/2015</td>
<td>Updated time frames (initial 6 months, continuation 1 year). This was due to a letter written from Dr Saper.</td>
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<td>1.3</td>
<td>Effective Date: 2/11/2016</td>
<td>Updated criteria for cervical dystonia and spasmodic torticollis to include functional impairment as a requirement</td>
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<td>1.4</td>
<td>Effective Date: 5/4/2017</td>
<td>Annual Review of Medical Policy</td>
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* 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](http://dailymed.nlm.nih.gov/dailymed/index.cfm)