

Medicare Advantage Medical Benefit Drug Policy



An independent licensee of the Blue Cross
and Blue Shield Association

Medical benefit drug policies are a source for Blue Cross and Blue Shield of Nebraska Medicare Advantage medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

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 the BCBSNE MA prior authorization list.
 - 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:

1. Lew MF et al. Botulinum toxin type B: a double-blind, placebo-controlled, safety and efficacy study in cervical dystonia. *Neurology* 1997;49:701-7.
2. Comella CL et al. Teaching tape for the motor section of the Toronto Western Spasmodic Torticollis Scale. *MovDisord* 1997;12(4):570-5.

3. Brashear A et al. Safety and efficacy of NeuroBloc (botulinumtoxin type B) in type A-responsive cervical dystonia. *Neurology* 1999;53:1439-46.
4. Brin MF et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-resistant cervical dystonia. *Neurology* 1999;53:1431-8.
5. Baumann L et al. A double-blinded, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc® (botulinum toxin type B)-purified neurotoxin complex for the treatment of crow's feet: a double-blinded, placebo-controlled trial. *DermatolSurg*2003;29(5):508-15.
6. OndoWG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. *Neurology* 2004;62(1):37-40.
7. Myobloc (botulinum toxin type B) [package insert]. Solstice Neurosciences, Inc., South San Francisco, CA. August 2009.
8. Baumann L, et al. Double-blind, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for the treatment of palmar hyperhidrosis. *Dermatol Surg.* 2005;31(3):263-70.
9. Baumann L, et al. Pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for treatment of axillary hyperhidrosis. *Int J Dermatol.* 2005;44(5):418-24.
10. Ghei M, et al. Effects of botulinum toxin B on refractory detrusor overactivity: a randomized, double-blind, placebo controlled, crossover trial. *J Urol.* 2005;174:1873-7.
11. Breuer B, Sperber K, Wallenstein S, et al. Clinically significant placebo analgesic response in a pilot trial of botulinum B in patients with hand pain and carpal tunnel syndrome. *Pain Medicine* 2006;7:16-24.
12. Botulinum Toxin Types A and B, Medicare Medical Policy, B2002.20R1; 5/2006.
13. Hirst GR et al. Botulinum toxin B is not an effective treatment of refractory overactive bladder. *Urology* 2007;69:69-73.
14. Sataloff RT et al. Botulinum toxin type B for the treatment of spasmodic dysphonia: a case report. *Journal of Voice* 2002; 16(3):422-24.
15. Dressler D et al. Botulinum toxin type B for treatment of axillary hyperhidrosis. *J Neurol* 2002; 249:1729-32.
16. Brashear A et al. Treatment with botulinum toxin type B for upper limb spasticity. *Arch Phys Med Rehabil* 2003;84:103-07.
17. Lagalla G, Millevolte M, Capecci M, Provinciali L, Ceravolo MG. Long-lasting benefits of botulinum toxin type B in Parkinson's disease-related drooling. *J Neurol.* 2009 Apr;256(4):563-7. Epub 2009 Apr 23.
18. Jackson CE, Gronseth G, Rosenfeld J, Barohn RJ, Dubinsky R, et al.; Muscle Study Group. Randomized double-blind study of botulinum toxin type B for sialorrhea in ALS patients. *Muscle Nerve.* 2009;39(2):137-43.
19. Schwerin A et al. Botulinum toxin B treatment in children with spastic movement disorders: a pilot study. *Pediatric Neurology* 2003; 31:109-13.
20. Sanger TD et al. Botulinum toxin type B improves the speed *Journal of Child Neurology* 2007; 22(1):116-22.
21. Hauser SL, Josephson SA, Harrison TR, Kasper DL, English JD, Braunwald E, Fauci AS, Engstrom JW, Longo DL, editors. *Harrison's Neurology in Clinical Medicine.* 16th ed. New York: McGraw-Hill Professional; 2006.
22. Basciani M, Di Rienzo F, Fontana A, Copetti M, Pellegrini F, Intiso D. Botulinum toxin type B for sialorrhea in children with cerebral palsy: a randomized trial comparing three doses. *Dev Med Child Neurol.* 2011 Jun;53(6):559-64.
23. Albanese A. Terminology for preparations of botulinum neurotoxins: what a difference a name makes. *JAMA.* 2012;305:89-90.
24. Myobloc (rimabotulinumtoxinB) [package insert]. Solstice Neurosciences, LLC., Louisville, KY. August 2019.

Policy/UM Medical Management System Update History		
#	Date	Change Description
1.3	Effective Date: 12/01/2022	Updated to include trial and failure of preferred products statement
1.2	Effective Date: 10/06/2022	Annual review of criteria was performed, no changes were made
1.1	Effective Date: 10/07/2021	Annual review of criteria was performed, no changes were made
1.0	Effective Date; 10/08/2020	Medical policy established

* 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>.