PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Myobloc (rimabotulinumtoxinB)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Myobloc is a neurotoxin produced from Clostridium botulinum. Myobloc works through the inhibition of acetylcholine release from peripheral nerve endings, causing neuromuscular blockage and muscle paralysis. It is the first and only botulinum toxin type B.
Myobloc was initially approved by the FDA in 2000 for the treatment of adults with cervical dystonia. Cervical dystonia (also known as spasmodic torticollis) involves the involuntary contractions of the neck that cause abnormal movements and postures of the neck and head.
Chronic sialorrhea, or excessive drooling, is a common symptom for patients with Parkinson's Disease or other neurological or cognitive impairments. Clinical trials showed a decrease in salivary production and improvement in symptoms from baseline with Myobloc.

Myobloc (rimabotulinumtoxinB) will be considered for coverage when the following criteria are met:

Cervical Dystonia

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or other specialist experienced with treating cervical dystonia; AND
3. Member has a documented diagnosis of moderate to severe cervical dystonia with dystonic symptoms localized to the head, neck, shoulder areas.
4. **Dosage allowed/Quantity limit:** Up to 5000 or 10,000 units every 12 to 16 weeks, divided among affected muscles.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improved severity, disability, or pain compared to baseline.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

Chronic Sialorrhea

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has diagnosis of chronic sialorrhea impacting quality of life for at least 3 months; AND
4. Member has tried and failed or has a contraindication to at least one anticholinergic drug (e.g. scopolamine, benztropine, glycopyrrolate, amitriptyline).
5. **Dosage allowed/Quantity limit:** 1,500 Units to 3,500 Units, divided among the parotid and submandibular glands, every 3 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Myobloc (rimabotulinumtoxinB) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/06/2018	New policy for Myobloc created. Age requirement removed. Criterion "no infection at proposed injection site" removed from Cervical Dystonia diagnosis. Age limitation removed from Cervical Dystonia; pain and abnormal head position requirements clarified and medications trial added.
06/09/2020	Added new diagnosis of chronic sialorrhea and its criteria.
08/17/2020	Cervical Dystonia: Added age limit and specialist requirement. Re-worded the diagnosis requirement. Removed trial of oral medication. Removed exclusions. Corrected the dose. Extended re-auth duration. Updated references.
01/04/2021	For sialorrhea, changed try 2 anticholinergics to try 1 anticholinergic. Added a reference.
08/10/2021	Transferred to new template. Allowing additional specialists for cervical dystonia indication.
03/04/2022	Annual review; no changes
11/13/2023	Removed "Symptoms affect quality of life and daily functions" for cervical dystonia; clarified renewal criteria and updated references.

References:

1. Myobloc [package insert]. San Francisco, CA: Solstice Neurosciences, Inc.; 2021.
2. Ondo WG, 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
3. Brashear A, Lew MF, Dykstra DD, et al. "Safety and Efficacy of NeuroBloc (Botulinum Toxin Type B) in Type A-Responsive Cervical Dystonia," Neurology, 1999, 53(7):1439-46
4. Isaacson S, Ondo W, Jackson C, et al. Safety and Efficacy of RimabotulinumtoxinB for Treatment of Sialorrhea in Adults. *JAMA Neurology*. 2020;77(4), 461. https://pubmed.ncbi.nlm.nih.gov/31930364/?dopt=Abstract.
5. Dashtipour K, Bhidayasiri, R, Chen J, et al. RimabotulinumtoxinB in sialorrhea: systematic review of clinical trials. *Journal of Clinical Movement Disorders*. 2017;4(1). https://clinicalmovementdisorders.biomedcentral.com/track/pdf/10.1186/s40734-017-0055-1.

6. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. *Neurology*. 2016;86(19):1818-1826. doi:10.1212/wnl.0000000000002560
7. Dressler D, Altenmueller E, Bhidayasiri R, et al. Strategies for treatment of dystonia. *Journal of Neural Transmission*. 2015;123(3):251-258. doi:10.1007/s00702-015-1453-x
8. Seppi K, Chaudhuri KR, Coelho M, et al. Update on treatments for nonmotor symptoms of Parkinson's disease—an evidence-based medicine review. *Movement Disorders*. 2019;34(2):180-198. doi:10.1002/mds.27602
9. Dashtipour K, Mari Z, Jankovic J, Adler CH, Schwartz M, Brin MF. Minimal clinically important change in patients with cervical dystonia: Results from the CD PROBE study. *J Neurol Sci*. 2019;405:116413. doi:10.1016/j.jns.2019.07.031
10. Dressler D, Adib Saberi F, Rosales RL. Botulinum toxin therapy of dystonia. *J Neural Transm (Vienna)*. 2021;128(4):531-537. doi:10.1007/s00702-020-02266-z

Effective date: 04/01/2024
Revised date: 11/13/2023