

PHARMACY POLICY STATEMENT

Marketplace

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| DRUG NAME | Myobloc (rimabotulinumtoxinB) |
| BILLING CODE | J0587 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office, Outpatient |
| 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. Multicenter, double-blind, placebo-controlled trials displayed a decrease in salivary production and improvement in symptoms from baseline.

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

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:

1. Member is 18 years old or older; 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 as evidenced by involuntary contractions of neck muscles, leading to abnormal movements or postures; AND
4. Symptoms affect quality of life and daily functions.
5. **Dosage allowed:** 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. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. severity of abnormal head position, neck pain).

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 18 years old or older; 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:** 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 | <u>Cervical Dystonia</u> : 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. |

References:

1. Myobloc [package insert]. San Francisco, CA: Solstice Neurosciences, Inc.; October 2019.
2. 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>.
3. 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>.
4. Cervical Dystonia. NORD (National Organization for Rare Disorders). <https://rarediseases.org/rare-diseases/cervical-dystonia/>. Published July 19, 2019. Accessed July 17, 2020.
5. 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
6. 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
7. 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

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