

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Myobloc (rimabotulinumtoxinB)
BILLING CODE	J0587
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office, Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see “Dosage Allowed”
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Myobloc (rimabotulinumtoxinB) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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; 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 sialorrhoea 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.

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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