

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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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