

PHARMACY POLICY STATEMENT

Georgia 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 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:

- Member has a pain or abnormal head position with documented turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis) causing adverse effect on daily functioning; AND
- Member has tried and failed one oral medication such as trihexyphenidyl (Artane), clonazepam (Klonopin), or baclofen; AND
- Member does **not** have any of the following:
 - Fixed contractures causing decreased neck range of motion;
 - Neuromuscular disease (e.g., myasthenia gravis);
 - Prior surgical treatment.
- Dosage allowed:** 2,500 to 5,000 Units divided among affected muscles.

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

For **reauthorization**:

- Member must be in compliance with all other initial criteria; AND
- Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 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 TWO anticholinergic drugs (e.g. scopolamine, benztropine, glycopyrrolate, amitriptyline); AND
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 shown 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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Tension headache, cervicogenic headache
- Myofascial pain syndrome
- Tremors such as benign essential tremor, chronic motor tic disorder and tics associated with Tourette Syndrome
- Parkinson's disease

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.

References:

1. Myobloc [package insert]. San Francisco, CA: Solstice Neurosciences, Inc.; October 2019.
2. MCG 20th Edition, 2016.
3. U.S. Drug and Food Administration Safety Data.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/125036s044lbl.pdf (March 6, 2011).
4. Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2011. (March 6, 2011).
5. 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.
6. Clinical Use of Botulinum Toxin," Arch Neurol, 1991, 48(12):1294-8.
7. Benecke R, Jost WH, Kanovsky P, et al, "A New Botulinum Toxin Type A Free of Complexing Proteins for Treatment of Dystonia," Neurology, 2005, 64(11):1949-51.

8. Borodic GE and Pearce LB, "New Concepts in Botulinum Toxin Therapy," *Drug Saf*, 1994, 11(3):145-52. Jankovic J and BrinMF, "Therapeutic Uses of Botulinum Toxin," *N Engl J Med*, 1991, 324(17):1186-94.
9. Naumann M and Jankovic J, "Safety of Botulinum Toxin Type A: A Systematic Review and Meta-Analysis," *Curr Med Res Opin*, 2004, 20(7):981-90.
10. Russman, BS, Tilton, A, Gormley ME. Jr. Cerebral palsy; a rational approach to a treatment protocol, and the role of botulinum toxin in treatment, *Muscle Nerve Suppl* 1997; 6:S181.
11. Fishman LM, Anderson C, Rosner B. Botox and physical therapy in the treatment of Piriformis syndrome *Am J Phys Med Rehabil*. 2002 Dec;81(12):936-42.
12. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. <http://www.guideline.gov/content.aspx?id=12942>(March 11 2011).
13. Simpson DM, et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70(19):1699-706.
14. Neumann M, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. *Neurology*. 2008; 70:1707-14.
15. Kean SJ, Muir VJ, Deeks ED. Botulinum toxin A (Dysport): in dystonias and focal spasticity. *Drugs* 2011;71(8):1043-58.
16. 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.
17. 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>.
18. 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>.

Effective date: 07/20/2020

Revised date: 06/09/2020