Clinical Policy: RimabotulinumtoxinB (Myobloc)

Reference Number: ERX.SPA.195
Effective Date: 01.11.17
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
RimabotulinumtoxinB (Myobloc®) is an acetylcholine release inhibitor and a neuromuscular blocking agent.

FDA Approved Indication(s)
Myobloc is indicated for the treatment of:
- Adults with cervical dystonia (CD) to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
- Adults with chronic sialorrhea

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Myobloc is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cervical Dystonia *(focal dystonia)* (must meet all)**:**
1. Diagnosis of CD;
2. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
3. Age ≥ 18 years;
4. Member is experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius capitis, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulders or head;
5. Contractions are causing pain and functional impairment;
6. Member meets both of the following (a and b):
   a. Myobloc is not prescribed concurrently with other botulinum toxin products;
   b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
7. Treatment plan provided detailing number of Units per indication and treatment session;
8. Dose does not exceed 5,000 Units per treatment session.

Approval duration: 12 weeks (single treatment session)

B. Chronic Sialorrhea (must meet all)**:**
1. Diagnosis of chronic sialorrhea for at least the last three months due to one of the following (a or b):
   a. Underlying neurologic disorder (e.g., Parkinson disease, atypical parkinsonism, stroke, traumatic brain injury, cerebral palsy, amyotrophic lateral sclerosis);
   b. Craniofacial abnormality (e.g., Goldenhar syndrome);
2. Prescribed by or in consultation with a neurologist or physiatrist;
3. Age ≥ 18 years;

4. Failure of at least one anticholinergic drug (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Member meets both of the following (a and b):
   a. Myobloc is not prescribed concurrently with other botulinum toxin products;
   b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
6. Treatment plan provided detailing number of Units per indication and treatment session;
7. Dose does not exceed 1,500 Units per parotid gland, 250 Units per submandibular gland, 3,500 units per treatment session.

Approval duration: 12 weeks (single treatment session)

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Cervical Dystonia (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member meets both of the following (a and b):
   a. Myobloc is not prescribed concurrently with other botulinum toxin products;
   b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
4. Treatment plan provided detailing number of Units per indication and treatment session;
5. If request is for a dose increase, new dose does not exceed 10,000 Units per treatment session.

Approval duration: 12 weeks (single treatment session)

B. Chronic Sialorrhea (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member meets both of the following (a and b):
   a. Myobloc is not prescribed concurrently with other botulinum toxin products;
   b. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
4. Treatment plan provided detailing number of Units per indication and treatment session;
5. If request is for a dose increase, dose does not exceed 1,500 Units per parotid gland, 250 Units per submandibular gland, 3,500 Units per treatment session.

Approval duration: 12 weeks (single treatment session)

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 weeks (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Cosmetic treatment of hyperfunctional wrinkles of the upper face including glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow's feet);

C. Same-visit treatment of multiple indications.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CD: cervical dystonia
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
glycopyrrolate (Glycate®)	1 mg PO TID	6 mg/day
benztropine (Cogentin®)	1 mg PO QD-BID	3.8 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications and Boxed Warnings
- Contraindication(s):
  - Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation
  - Infection at the proposed injection site
- Boxed warning(s): distant spread of toxin effect

Appendix D: Botulinum Toxin Product Interchangeability
- Potency Units of Myobloc are not interchangeable with other botulinum toxin product preparations (e.g., Dysport®, Botox®, Xeomin®).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	Divided among affected muscles every 12 weeks: • Initial dose: Up to 5,000 Units IM • Subsequent dose: Up to 10,000 Units IM	10,000 Units/12 weeks
Chronic sialorrhea	Up to 1,500 Units IM per parotid gland, 250 Units IM per submandibular gland, and 3,500 Units IM per treatment session every 12 weeks.	3,500 Units/12 weeks

VI. Product Availability

Vials: 2,500 Units/0.5 mL, 5,000 Units/1 mL, 10,000 Units/2 mL

VII. References

1. Myobloc Prescribing Information. Rockville, MD: Solstice Neurosciences, Inc.; August 2019. Available at https://myobloc.com/files/MYOBLOC_PI.pdf. Accessed February 1, 2022.
2. RimabotulinumtoxinB. In: Micromedex. Ann Arbor, MI: Truven Health Analytics; 2020. Available from: www.micromedexsolutions.com. Accessed February 1, 2022.

Dystonia

3. 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: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016; 86(19): 1818-1826.
4. Albanese A, Bhatia K, Bressman SB, et al. Phenomenology and classification of dystonia: a consensus update. Mov Disord. June 15, 2013; 28(7): 863-873. doi:10.1002/mds.25475.
5. Cloud LJ, Jinnah HA. Treatment strategies for dystonia. Expert Opin Pharmacother 2010; 11(1):5-15.

Sialorrhea
6. Isaacson SH, Ondo W, Jackson CE et al. Safety and efficacy of rimabotulinumtoxinB for treatment of sialorrhea in adults: a randomlized clinical trial. JAMA Neurol. 2020; 77 (4):461-469. Dol: 1.1001/jamaneurol.2019.4565.
7. Seppi K, Chahine L, Chaudhuri R et al. International Parkinson and Movement Disorder Society evidence-based medicine review: Update on treatments for the non-motor symptoms of Parkinson's Disease. 2018. Available at https://www.movementdisorders.org/MDS-Files1/Resources/PDFs/EBM-NMS-Final-Paper-August-2018.pdf.
8. Sridharan K, Sivaramakrishnan G. Pharmacological interventions for treating sialorrhea associated with neurological disorders: A mixed treatment network meta-analysis of randomized controlled trials. Journal of Clinical Neuroscience 51 (2018) 12–17.
9. Lakraj AA, Moghimi, Jabbari B. Sialorrhea: Anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxins. Toxins 2013, 5, 1010-1031; doi:10.3390/toxins5051010.
10. Young CA, Johnson EC, et al. Treatment for sialorrhea (excessive saliva) in people with motor neuron disease/amyotrophic lateral sclerosis. Cochrane Database Syst Rev. 2011 May 11;(5):CD006981. doi: 10.1002/14651858.CD006981.pub2.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: added physical medicine and rehabilitation specialist; required provider submission of treatment plan; required specific clinical signs of diagnosis; references reviewed and updated.	02.09.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.05.19	05.19
Criteria added for new FDA indication: chronic sialorrhea; added Medicaid line of business; references reviewed and updated.	10.08.19	02.20
2Q 2020 annual review: rehabilitation specialist incorporated under physiatrist; previous (last 12 weeks) or concurrent toxin product use restriction added to all initial/continuation criteria; dosing updated per package insert; same-visit treatment for multiple indications is excluded (Section III); references reviewed and updated.	03.02.20	05.20
2Q 2021 annual review: no significant changes; treatment plan requirement detailing number of Units per site and treatment session is changed to per indication and treatment session; references reviewed and updated.	03.04.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	02.01.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.