Clinical Policy: RimabotulinumtoxinB (Myobloc)

Reference Number: ERX.SPA.195
Effective Date: 01.11.17
Last Review Date: 05.18 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 to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

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.

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 (must meet all)**:**

1. Diagnosis of CD (*see Appendix C*);
2. Prescribed by or in consultation with a neurologist, orthopedist, physiatrist, or physical medicine and rehabilitation specialist;
3. Age ≥ 18 years;
4. 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. Provider submits treatment plan detailing the quantity (in units) of Myobloc to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
7. Dose does not exceed 10,000 units per treatment session.

Approval duration: 12 weeks (single treatment session)

B. 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. It has been at least 12 weeks since the last injection of Myobloc;
4. Provider submits treatment plan detailing the quantity (in units) of Myobloc to be injected in each muscle site, anticipated frequency of injection, and total dose per visit;
5. If request is for a dose increase, new dose does not exceed 10,000 units per single treatment session.

Approval duration: 12 weeks (single treatment session)

B. 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: 12 weeks (single treatment session); 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).

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Definition and Classification of Dystonia [3]
Dystonia is defined as a movement disorder characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements, postures, or both.

- Dystonic movements are typically patterned and twisting, and may be tremulous.
- Dystonia is often initiated or worsened by voluntary action and associated with overflow muscle activation.

Dystonia is classified along two axes:

- Clinical characteristics: Age at onset, body distribution, temporal pattern, associated features (additional movement disorders or neurological features) - *the clinical characteristics fall into several specific dystonia syndromes that help to guide diagnosis and treatment*;
- Etiology: Nervous system pathology, inheritance.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	The initial dose of Myobloc for patients with a history of tolerating botulinum toxin injections is 2,500 to 5,000 U divided among affected muscles. Give patients without a history of tolerating botulinum toxin injections a lower initial dose. Optimize subsequent dosing according to the patient's individual response. The duration of effect has been observed in studies to be between 12 and 16 weeks at doses of 5000 U or 10,000 U.	10,000 units/12 weeks

VI. Product Availability
Vials: 2,500 units, 5,000 units, 10,000 units

VII. References

1. Myobloc Prescribing Information. South San Francisco, CA: Solstice Neurosciences, Inc.; May 2010. Available at http://www.myobloc.com/hp_about/PI_5-19-10.pdf. Accessed February 16, 2018.
2. 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.
3. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.01.16	01.17
4Q17 Annual Review - Converted to new template. - Added age limit requirements. - Added requirement for documentation of positive response to therapy, for reauthorization.	10.03.17	11.17
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

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.