Clinical Policy: RimabotulinumtoxinB (Myobloc)

Reference Number: PA.CP.PHAR.233
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

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 CD.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Myobloc is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Cervical Dystonia (must meet all):
1. Diagnosis of cervical dystonia (*see definition in Appendix D*);
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 or functional impairment;
6. Provider submits treatment plan detailing the quantity (in units) of Myobloc to be injected in each muscle site;
7. Prescribed dose of Myobloc does not exceed 10,000 units per treatment session.

Approval duration: 12 weeks (single treatment session)

B. Other diagnoses/indications:
1. Refer to PA.CP.PMN.53 if requested indication is non-cosmetic.

II. Continued Approval

A. Cervical Dystonia (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Provider submits treatment plan detailing the quantity (in units) of Myobloc to be injected in each muscle site;
4. Prescribed dose of Myobloc does not exceed 10,000 units per treatment session.

Approval duration: 12 weeks (single treatment session)

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: 12 weeks (single treatment session); or
2. Refer to PA.CP.PMN.53; coverage is not approved for cosmetic use, including for treatment of glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow's feet).

III. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
Not applicable

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: 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.

IV. 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.	10,000 units/12 weeks

Indication	Dosing Regimen	Maximum 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.	

V. Product Availability

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

VI. 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 January 25, 2019.
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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0587	Injection, rimabotulinumtoxinB, 100 units

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed requirement of at least 12 weeks have passed since last treatment; references reviewed and updated.	2.9.18	
2Q 2019 annual review: added physical medicine and rehabilitation specialist for cervical dystonia; references reviewed and updated.	04/19	