RXADVANCE
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Clinical Policy Title:	rimabotulinumtoxinB
Policy Number:	RxA.412
Drug(s) Applied:	Myobloc®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

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.
- For the treatment of adults with chronic sialorrhea.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
RimabotulinumtoxinB (Myobloc®)	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/12weeks
	Chronic sialorrhea	Recommended dosage is 1,500 to 3,500 U; 500Uto 1,500 U per parotid gland and 250 U per submandibular gland; no more frequent than every 12 weeks.	5,000 units/12weeks

Dosage Forms

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

Clinical Policy

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

I. Initial Approval Criteria

1. Cervical Dystonia (must meet all):

1. Diagnosis of CD (*see 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 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
Commercial: 6 months
Medicaid: 84 days (single treatment session)

2. 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, orthopedist 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. Dose does not excess 1,500 Units per parotid gland, 250 Units per submandibular gland, 3,500 Units per treatment session.

Approval Duration
Commercial: 6 months
Medicaid: 84 days (single treatment session)

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving the medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy 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, request meets one of the following (a, b)
   a. Cervical Dystonia: new dose does not exceed 10,000 units per treatment session.
   b. Chronic Sialorrhea: new dose does not exceed 1,500 units per parotid gland, 250 units per submandibular gland, 3,500 units per treatment session.

Approval Duration
Commercial: 12 months
Medicaid: 84 days (single treatment session)

III. Appendices

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dose Regimen	Dose Limit/Maximum Dose
glycopyrrolate (Glycate®)	1 mg PO TID	6 mg/day
benztropine (Cogentin®)	1 mg PO OD-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/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: General Information
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.

References

1. Myobloc Prescribing Information. Louisville, KY: Solstice Neurosciences, Inc.; August 2019. Available at http://www.myobloc.com/files/MYOBLOC PI.pdf. Accessed July 19, 2020.
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. Accessed July 19, 2020.
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. Accessed July 19, 2020.
4. 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. Accessed July 19, 2020.
5. 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. Accessed July 19, 2020.
6. 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. Accessed July 19, 2020.
7. 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. Accessed July 19, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Dosing information was updated. 3. Initial approval criteria were updated. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. Appendices updated. 6. References were updated.	07/19/2020	09/14/2020