Clinical Policy Title:	rimabotulinumtoxinB
Policy Number:	RxA.412
Drug(s) Applied:	Myobloc®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Myobloc® is an acetylcholine release inhibitor indicated for:

- Treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia (CD) in adults.
- Treatment of chronic sialorrhea in adults.

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 units 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 units or 10,000 units.	10,000 units/12weeks
	Chronic sialorrhea	Recommended dosage is 1,500 to 3,500 units; 500 units to 1,500 units per parotid gland and 250 units per submandibular gland; no more frequent than every 12 weeks.	3500 units/12weeks

Dosage Forms

- Vials: 2,500 units/0.5 mL, 5,000 units/1 mL, 10,000 units/2 mL, (5,000 Units/mL) in a single-dose vial.

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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. 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. 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. 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;
8. Dose does not exceed 10,000 units per treatment session.

Approval Duration
Commercial: 6 months
Medicaid: 84 days (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, 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 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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dose Regimen	Dose Limit/Maximum Dose
glycopyrrolate (Glycate®)	1 mg orally three times daily	6 mg/day
benztropine (Cogentin®)	1 mg orally once to twice daily	3.8 mg/day

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

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.
- Spread of toxin effects; swallowing and breathing difficulties can lead to death. Seek immediate medical attention if respiratory, speech or swallowing difficulties occur.
- Myobloc® potency units cannot be compared to or converted into units of other botulinum toxins.
- Patients with neuromuscular disorders should be monitored closely for swallowing/breathing difficulty.

- 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

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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
Policy was reviewed:	06/25/2021	09/14/2021

1. Background was updated to remove “Myobloc is an acetylcholine release inhibitor and a neuromuscular blocking agent.” 2. Dosing Information maximum dose for indication chronic sialorrhea was updated from “5000 units/12 weeks” to “3500 Units/12 weeks”. 3. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 4. Initial Approval Criteria I.A.3 was updated to remove “Member has a prior history of tolerating botulinum toxin injection…” 5. Initial Approval Criteria I.A.6 was updated to include “Member meets both of the following (a and b)…”. 6. . 7. Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…” 8. Appendix B: Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 9. Statement about drug listing format in Appendix B is updated to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 10. Appendix D was updated to include “Spread of toxin effects; swallowing and breathing difficulties…”, “Myobloc® potency units cannot be compared to or converted…”, and “Patients with neuromuscular disorders should be monitored…”. 11. References were reviewed and updated.		