Clinical Policy: RimabotulinumtoxinB (Myobloc)

Reference Number: CP.PHAR.233
Effective Date: 07.01.16
Last Review Date: 05.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
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 CD
- 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.

It is the policy of health plans affiliated with Centene Corporation® that Myobloc is **medically necessary** when one of 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. Failure of Botox® and Dysport®, unless clinically significant adverse effects are experienced or both are contraindicated;
7. Myobloc is not prescribed concurrently with other botulinum toxin products;
8. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
9. Treatment plan provided detailing number of Units per indication and treatment session;
10. Dose does not exceed 5,000 Units per treatment session.

Approval duration:
Medicaid/HIM – 12 weeks (single treatment session)

Commercial – 6 months or to the member's renewal date, whichever is longer

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. Failure of Xeomin®, unless contraindicated or clinically significant adverse effects are experienced;
6. Myobloc is not prescribed concurrently with other botulinum toxin products;
7. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
8. Treatment plan provided detailing number of Units per indication and treatment session;
9. Dose does not exceed 1,500 Units per parotid gland, 250 Units per submandibular gland, 3,500 units per treatment session.

Approval duration:
Medicaid/HIM – 12 weeks (single treatment session)
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Approval

A. Cervical Dystonia (must meet all)**:**
1. Member meets one of the following (a or b):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

2. Member is responding positively to therapy;
3. Myobloc is not prescribed concurrently with other botulinum toxin products;
4. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
5. Treatment plan provided detailing number of Units per indication and treatment session;
6. If request is for a dose increase, new dose does not exceed 10,000 Units per treatment session.

Approval duration:
Medicaid/HIM – 12 weeks (single treatment session)
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Chronic Sialorrhea (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Myobloc is not prescribed concurrently with other botulinum toxin products;
4. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
5. Treatment plan provided detailing number of Units per indication and treatment session;
6. 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:
Medicaid/HIM – 12 weeks (single treatment session)
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid;

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
glycopyrrolate (Glycate®)	Chronic Sialorrhea: 1 mg PO TID	6 mg/day
benztropine (Cogentin®)	Chronic Sialorrhea: 1 mg PO QD-BID	3.8 mg/day
Xeomin® (incobotulinumtoxinA)	Chronic Sialorrhea: Up to 30 Units IM per parotid gland, 20 Units IM per submandibular gland, and 100 Units IM per treatment session every 16 weeks.	100 Units/16 weeks
Dysport® (abobotulinumtoxin A)	Cervical Dystonia: Divided among affected muscles every 12 weeks: Up to 1,000 Units IM	See dosing regimen
Botox® (OnabotulinumtoxinA)	Cervical Dystonia: Up to 50 Units IM per injection, 100 Units total in the sternocleidomastoid	See dosing regimens for maximum dose

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	(SCM) muscle, and 300 Units per treatment session	Frequency: One treatment session every 12 weeks

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.; March 2021. Available at https://www.myobloc.com/files/Myobloc-Prescribing-Information.pdf. Accessed January 18, 2024.
2. RimabotulinumtoxinBs. In: Micromedex. Ann Arbor, MI: Truven Health Analytics; 2020. Available from: www.micromedexsolutions.com. Accessed February 16, 2024.

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.
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.
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.

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	P&T Approval Date
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
Per October SDC and prior clinical guidance, added the following redirections: Xeomin and Dysport for cervical dystonia, Xeomin for chronic sialorrhea.	10.08.20	
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; revised HIM-Medical Benefit to HIM line of business; references reviewed and updated.	03.04.21	05.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Ad Hoc update: max dose for Xeomin in Appendix B updated to 300 mg for CD per PI.	07.26.21	
2Q 2022 annual review: no significant changes; revised Commercial approval duration from "6 months" (or whatever it is now) to the current standard for injectables of "6 months or to member's renewal date, whichever is longer"; removed in Section III "Ambetter, hyperhidrosis is a benefit exclusion categorized as a cosmetic service"; references reviewed and updated.	02.01.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.07.22	
2Q 2023 annual review: Per February SDC and prior clinical guidance, for cervical dystonia replaced Xeomin redirection with Botox to co-prefer with Dysport; references reviewed and updated.	02.21.23	05.23
2Q 2024 annual review: no significant changes; in continued therapy revised Commercial approval duration from "12 months" to the current standard for injectables of "6 months or to member's renewal date, whichever is longer"; references reviewed and updated.	01.18.24	05.24

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.