

JURISDICTION SPECIFIC MEDICARE PART B

Myobloc (rimabotulinumtoxin B)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- A. Cervical dystonia
- B. Chronic sialorrhea

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. Medical record must support the use of the selected ICD-10-CM code(s). Submitted CPT/HCPCS code must describe the service performed
- B. Documentation of unsuccessful, inadequate response, or not a candidate for conventional methods of treatment and/or other appropriate methods used to control condition as applicable (a statement outlining relevant medical history is acceptable)
- C. Results of pertinent tests/procedures
- D. Type of botulinum toxin used, strength of toxin, dosage and frequency of injections
- E. Support for the clinical effectiveness of the injections
- F. Support for the medical necessity of localization procedures if performed
- G. Site(s) injected

IV. CRITERIA FOR APPROVAL

A. Cervical Dystonia

Authorization of 12 months may be granted for the treatment of cervical dystonia in adults.

B. Chronic sialorrhea

| Reference number(s) |
|---------------------|
| 2165-A |

Authorization of 12 months may be granted for the treatment of chronic sialorrhea in adults.

V. DOSAGE AND ADMINISTRATION

The lowest effective dose and longest dosing interval that produces the desired clinical effect should be used.

VI. REFERENCES

1. Botulinum Toxins LCD (L33274) Version R11. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 16, 2021.
2. Billing and Coding: Botulinum Toxins (A57715) Version R1. Available at: Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 16, 2021.
3. Myobloc [package insert]. Louisville, KY: Solstice Neurosciences, LLC; March 2021.

DOCUMENT HISTORY

Created: Specialty Clinical Development (NU) 08/2018
Revised: JL 08/2019, LP 08/2020, LP 02/2021 (LCD revision), NU 08/2021
Reviewed: CDPR/DNC 09/2018, EPA 08/2019, AN 08/2020, AN 11/2020, 02/2021, SNG 08/2021
External Review: 10/2018, 10/2019, 09/2020, 03/2021, 10/2021