Draft Revised Policy: Do Not Implement

RimabotulinumtoxinB (Myobloc®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

INDICATIONS

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

FDA-Approved Indications

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

Compendial Uses

- Primary axillary and palmar hyperhidrosis
- Upper limb spasticity

All other indications are considered experimental/investigational and not medically necessary.

EXCLUSIONS

Coverage will not be provided for cosmetic use.

COVERAGE CRITERIA

Cervical Dystonia
Authorization of 12 months may be granted for treatment of adults with cervical dystonia (e.g., torticollis) when all of the following are met:

- Member is 18 years of age or older
- Member has abnormal placement of the head with limited range of motion in the neck

Chronic Sialorrhea (excessive salivation)
Authorization of 12 months may be granted for treatment of chronic sialorrhea (excessive salivation) when all of the following are met:

- Member is 18 years of age or older
- Member is refractory to pharmacotherapy (e.g., anticholinergics)

Primary Axillary and Palmar Hyperhidrosis
Authorization of 12 months may be granted for treatment of primary axillary or palmer hyperhidrosis when all of the following criteria are met:

- Significant disruption of professional and/or social life has occurred because of excessive sweating; and
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

Upper Limb Spasticity
Authorization of 12 months may be granted for treatment of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria and be experiencing benefit from therapy.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Myobloc (RimabotulinumtoxinB)	Cervical Dystonia	Route of Administration: Intramuscular ≥18 year(s) 10000Units divided among the affected muscles. May re-treat no sooner than every 12 weeks.
Myobloc (RimabotulinumtoxinB)	Chronic Sialorrhea	Route of Administration: Injection ≥18 year(s) 3500Units divided among the parotid and submandibular glands. May re-treat no sooner than every 12 weeks.
Myobloc (RimabotulinumtoxinB)	Palmar Hyperhidrosis	Route of Administration: Intradermal 9000 ~~5000~~Units per palm. May re-treat no sooner than every 12 weeks.
Myobloc (RimabotulinumtoxinB)	Primary Axillary Hyperhidrosis	Route of Administration: Intradermal 4000 Units per axilla. May re-treat no sooner than every 12 weeks.
Myobloc (RimabotulinumtoxinB)	Upper Limb Spasticity	Route of Administration: Intramuscular 15000Units divided among the affected muscles. May re-treat no sooner than every 12 weeks.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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4. Lexi-Drugs. Hudson, OH: Lexicomp, 2019. http://online.lexi.com/. Accessed August 14, 2024.
5. 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.
6. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. Toxins 2013, 5, 1010-1031
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EFFECTIVE DATE

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