



## Medical Policy Manual **Approved Rev: Do Not Implement until 7/2/24**

### Rimabotulinumtoxin B (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.

#### POLICY

##### I. 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.

###### A. FDA-Approved Indications

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

###### B. Compendial Uses

1. Primary axillary and palmar hyperhidrosis
2. Upper limb spasticity

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

##### II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

##### III. CRITERIA FOR INITIAL APPROVAL

###### A. **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:

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

###### B. **Chronic Sialorrhea (excessive salivation)**

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

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

###### C. **Primary axillary and palmar hyperhidrosis**

Authorization of 12 months may be granted for treatment of primary axillary or palmar hyperhidrosis when all of the following criteria are met:

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

### **D. 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.

## **IV. CONTINUATION OF THERAPY**

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

### **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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