POLICY Document for MYOBLOC (rimabotulinumtoxin B)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
BOTULINUM TOXINS

PREFERRED PRODUCTS: DYSPORT, XEOMIN

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the botulinum toxins products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Botulinum Toxins

	Product(s)
Preferred*	• **Dysport** (abobotulinumtoxinA) • **Xeomin** (incobotulinumtoxinA)
Targeted	• **Botox** (onabotulinumtoxinA) • **Myobloc** (rimabotulinumtoxinB) • **Daxxify** (daxibotulinumtoxinA)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for Botox is provided when ANY of the following criteria is met:
A. Request is not for spasticity or cervical dystonia in adult patients, or blepharospasm
B. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Coverage for Myobloc is provided when ANY of the following criteria is met:
A. Member has a documented inadequate response, contraindication, or intolerable adverse event to Xeomin for chronic sialorrhea in patients ≥ 12 years of age
B. Member has a documented inadequate response, contraindication, or intolerable adverse event to Dysport and Xeomin for cervical dystonia in adult patients.

Coverage for Daxxify is provided when ANY of the following criteria is met:
A. Member has a documented inadequate response, contraindication, or intolerable adverse event to Dysport and Xeomin for cervical dystonia in adult patients.

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

MYOBLOC (rimabotulinumtoxin B)

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. PRESCRIBER SPECIALTIES

The medication must be prescribed by, or in consultation with the following for each indication:
A. Cervical dystonia and upper limb spasticity: neurologist, orthopedist or physiatrist
B. Chronic sialorrhea: neurologist or otolaryngologist
C. Primary axillary and palmar hyperhidrosis: neurologist, internist or dermatologist

III. EXCLUSIONS

Coverage will not be provided for cosmetic use.

IV. 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 palmer hyperhidrosis when all of the following criteria are met:
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.

V. 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.

REFERENCES:

SECTION 1

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2. Daxxify [package insert]. Newark, CA: Revance Therapeutics, Inc; August 2023.
3. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2023.
4. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
5. Xeomin [package insert]. Frankfurt, Germany: Merz Pharmaceuticals GmbH; September 2023.

SECTION 2

1. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com. Accessed July 28, 2023.
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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.
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7. Glader L, Delsing C, Hughes A et al. Sialorrhea in cerebral palsy. American Academy for Cerebral Palsy and Developmental Medicine Care Pathways. https://www.aacpdm.org/publications/care-pathways/sialorrhea. Accessed July 28, 2023.
8. Garuti G, Rao F, Ribuffo V et al. Sialorrhea in patients with ALS: current treatment options. *Degener Neurol Neuromuscul Dis*. 2019; 9: 19–26.