POLICY Document for Daxxify

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
Daxxify

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Daxxify	daxibotulinumtoxinA-lanm

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

- The treatment of cervical dystonia in adult patients.

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

Prescriber Specialties

The medication must be prescribed by, or in consultation with a provider specialized in treating the member's condition.

Exclusions

Coverage will not be provided for cosmetic use.

Coverage Criteria

Cervical dystonia

Authorization of 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when both of

the following are met:

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

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.

REFERENCES:

SECTION 1

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; August 2023.
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. Daxxify [package insert]. Newark, CA: Revance Therapeutics, Inc; November 2023.