EXCEPTIONS CRITERIA

BOTULINUM TOXINS

PREFERRED PRODUCTS: DYSPORT AND XEOMIN

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 products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

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)

*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 product.

Coverage for a targeted product is provided when ANY of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response or intolerable adverse event to both of the preferred products.
C. Member is requesting Botox for the treatment of blepharospasm and either of the following criteria is met:
    1. Member is 18 years of age and older and the member has had a documented inadequate response or intolerable adverse event to Xeomin
    2. Member is 12 years of age or older but less than 18 years of age

D. Member is requesting Botox for the treatment of lower limb spasticity and has had a documented inadequate response or adverse event to Dysport.
E. Member is requesting Botox for the treatment of upper limb spasticity and both of the following criteria are met:
    1. Member is a pediatric patient 2 years of age to 17 years of age and the upper limb spasticity is caused by cerebral palsy.
    2. Member has had a documented inadequate response or adverse event to Dysport.
F. Member is requesting Myobloc for the treatment of chronic sialorrhea and has had a documented inadequate response or an intolerable adverse event to Xeomin.

REFERENCES

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; July 2021.
2. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2020.
3. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
4. Xeomin [package insert]. Frankfurt, Germany: Merz Pharmaceuticals GmbH; August 2021.

