Reference number(s)
4248-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Botulinum Toxins

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the botulinum toxins products specified in this document. Coverage for the non-preferred 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 non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Botulinum Toxins

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Dysport (abobotulinumtoxinA) • Xeomin (incobotulinumtoxinA)
Non-preferred	• Botox (onabotulinumtoxinA) • Myobloc (rimabotulinumtoxinB)

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Step Therapy Criteria

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

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member has a documented inadequate response or intolerable adverse event to both of the preferred products.
- Member is requesting Botox for the treatment of blepharospasm and either of the following criteria is met:
    - Member is 18 years of age and older and the member has had a documented inadequate response or intolerable adverse event with Xeomin
    - Member is 12 years of age or older but less than 18 years of age
- Member is requesting Botox for the treatment of lower limb spasticity and has had a documented inadequate response or adverse event to Dysport.
- Member is requesting Botox for the treatment of upper limb spasticity and both of the following criteria are met:
    - Member is a pediatric patient 2 years of age to 17 years of age and the upper limb spasticity is caused by cerebral palsy.
    - Member has had a documented inadequate response or adverse event with Dysport.
- Member is requesting Myobloc for the treatment of chronic sialorrhea and has had a documented inadequate response or an intolerable adverse event with Xeomin.

References

1. Botox [package insert]. North Chicago, IL: Allergan, Inc., an AbbVie company; November 2023.
2. Dysport [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, LLC; September 2023.
3. Myobloc [package insert]. Rockville, MD: Solstice Neurosciences, Inc.; March 2021.
4. Xeomin [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; July 2024.

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