Reference number(s)
4980-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Botulinum Toxins

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

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), and Advanced Control Specialty – Choice Formulary (ACSCF).

Plan Design Summary

This program applies to the botulinum toxins products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. For chronic migraine, this program applies to all members who are new to treatment with Botox for the first time. For all other indications, 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. Chronic Migraine

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

	Products
Preferred	• Ajovy (fremanezumab-vfrm injection) • Emgality 120 mg (galcanezumab-gnlm injection) • Qulipta (atogepant)
Targeted	• Botox (onabotulinumtoxinA)

Table. Botulinum Toxins – All Other Indications

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

	Products
Preferred	• Daxxify (daxibotulinumtoxinA-lanm) • Xeomin (incobotulinumtoxinA)
Targeted	• Botox (onabotulinumtoxinA) • Dysport (abobotulinumtoxinA) • Myobloc (rimabotulinumtoxinB)

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 are met:

Botox

Coverage for Botox is provided when any of the following criteria is met:

- Member has a documented inadequate response or intolerable adverse event to both of the preferred products, Daxxify and Xeomin.
- Member is requesting Botox for the treatment of lower limb spasticity.
- Member is 18 years of age or older, is requesting Botox for the treatment of upper limb spasticity, and has had a documented inadequate response or an intolerable adverse event to Xeomin.
- Member is a pediatric patient 2 years of age to 17 years of age and is requesting Botox for the treatment of upper limb spasticity that is caused by cerebral palsy.
- Member is requesting Botox for the treatment of blepharospasm and either of the following criteria are met:
    - Member is 18 years of age and older and has 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 preventative treatment of chronic migraine and either of the following criteria is met:

- Member is currently receiving treatment with the targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with one of the preferred calcitonin gene-related peptide (CGRP) receptor antagonist products listed.

Dysport

Coverage for Dysport is provided when any of the following criteria is met:

- Member has a documented inadequate response or intolerable adverse event to both of the preferred products, Daxxify and Xeomin.
- Member is requesting Dysport for the treatment of lower limb spasticity.
- Member is 18 years of age or older, is requesting Dysport for the treatment of upper limb spasticity, and has had a documented inadequate response or an intolerable adverse event to Xeomin.
- Member is a pediatric patient 2 years of age to 17 years of age and is requesting Dysport for the treatment of upper limb spasticity that is caused by cerebral palsy.

Myobloc

Coverage for Myobloc is provided when any of the following criteria is met:

- Member has a documented inadequate response or intolerable adverse event to both of the preferred products, Daxxify and Xeomin.
- Member is requesting Myobloc for the treatment of chronic sialorrhea and has a documented inadequate response or 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.
5. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2022.
6. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2021.
7. Qulipta [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.