This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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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 with 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 a documented inadequate response or intolerable adverse event with Xeomin.
   2. Member is 12 years of age or older but less than 18 years of age.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

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D. Member is requesting Botox for the treatment of lower limb spasticity and has a documented inadequate response or intolerable adverse event with 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 a documented inadequate response or intolerable adverse event with Dysport.
F. 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; September 2023.