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

Reference #
3304-D

EXCEPTIONS CRITERIA
HEREDITARY ANGIOEDEMA

PREFERRED PRODUCT: RUCONEST

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 hereditary angioedema 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 all members requesting treatment with a targeted product

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. C1 esterase inhibitors for the treatment of acute attacks of hereditary angioedema

	Products
Preferred*	• **Ruconest** (C1 esterase inhibitor [recombinant])
Targeted	• **Berinert** (C1 esterase inhibitor [human])

*: 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 the targeted product is provided when any of the following criteria is met:

A. Member is using the targeted product for short-term preprocedural prophylaxis (i.e., prior to surgical or major dental procedures).
B. Member has a documented inadequate response to the preferred product.
C. Member has a documented intolerable adverse event with the preferred product.
D. Member has a documented contraindication to the preferred product (i.e., known or suspected allergy to rabbits or rabbit-derived products).
E. Member is less than 13 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: Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**	✓	**Medical Benefit: Managed Medicaid**		**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
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F. Targeted product is being requested for treatment of laryngeal attacks.

REFERENCES

1. Ruconest [package insert]. Warren, NJ: Pharming Healthcare, Inc.; April 2020.
2. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September 2021.