This policy applies to the following:

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

Reference #
3303-D

EXCEPTIONS CRITERIA
HEREDITARY ANGIOEDEMA

PREFERRED PRODUCTS: ICATIBANT, 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. Products for the treatment of acute attacks of hereditary angioedema

	Products
Preferred*	• **icatibant** (generic) • **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 tried and experienced a documented inadequate response to both of the preferred products.
C. Member has tried and experienced a documented intolerable adverse event with both of the preferred products.
D. Member has tried and experienced a documented inadequate response or intolerable adverse event to icatibant and the requested product is being requested for treatment of laryngeal attacks.
E. Member has tried and experienced a documented inadequate response or intolerable adverse event to icatibant and the member has a documented contraindication to Ruconest (i.e., known or suspected allergy to rabbits or rabbit-derived products).

This policy applies to the following:

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

Reference #
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F. Member is less than 13 years of age.

G. The member is 13 years of age or older but less than 18 years of age and the member meets any of the following:
   1. The member has tried and experienced a documented inadequate response or intolerable adverse event to Ruconest.
   2. The requested product will be used for the treatment of laryngeal attacks.
   3. The member has a documented contraindication to Ruconest (i.e., known or suspected allergy to rabbits or rabbit-derived products).

REFERENCES

1. icatibant [package insert]. Tainan City, Taiwan: Nang Kuang Pharmaceutical Co., LTD; August 2020.
2. Ruconest [package insert]. Raleigh, NC: Santarus, Inc.; April 2020.
3. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; March 2021.