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POLICY Document for Berinert (C1 Inhibitor, Human)

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
HEREDITARY ANGIOEDEMA

I. PREFERRED PRODUCT: RUCONEST

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

II. PLAN DESIGN SUMMARY

This program applies to the hereditary angioedema products specified in this policy. Coverage for the non-preferred product 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 the non-preferred 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

	Product(s)
Preferred	• **Ruconest** (C1 esterase inhibitor [recombinant])
Non-Preferred	• **Berinert** (C1 esterase inhibitor [human])

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III. EXCEPTION CRITERIA

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

A. Member is currently receiving treatment with the non-preferred product through health insurance, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
B. Member has tried and experienced an inadequate response to the preferred product.
C. Member has tried and experienced an intolerable adverse event to the preferred product.
D. Member has a 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.
F. Non-preferred product is being requested for treatment of laryngeal attacks.

Section 2: Clinical Criteria

BERINERT (C1 Inhibitor, Human) Enhanced Specialty Guideline Management

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) in adult and pediatric patients.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: C4 levels and C1 inhibitor functional and antigenic protein levels.

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of HAE attacks when any of the following criteria are met:

1. Member has C1 inhibitor deficiency as confirmed by laboratory testing.
2. Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
   a. Member has an F12 gene mutation as confirmed by genetic testing or
   b. Member has a family history of angioedema and the angioedema was refractory to a trial of antihistamine (e.g., cetirizine) for at least one month.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of therapy when all of the following criteria are met:

1. Member meets the criteria for initial approval.
2. Member has experienced reduction in severity and duration of attacks since starting treatment.

REFERENCES:

SECTION 1

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2. Ruconest [package insert]. Raleigh, NC: Santarus, Inc.; February 2015.

SECTION 2

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