Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Acute Hereditary Angioedema Products: Berinert, Kalbitor, Firazyr, and Ruconest***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Acute Hereditary Angioedema Products: Berinert, Kalbitor, Firazyr, and Ruconest.

- C1 Esterase Inhibitor [human] (Berinert) is indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and pediatric patients.
- Ecallantide (Kalbitor) is approved for the treatment of acute attacks of HAE in patients 12 years and older.
- Icatibant (Firazyr) is indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
- C1 Esterase Inhibitor [recombinant] (Ruconest) is indicated for the treatment of acute attacks in adult and adolescent patients with HAF.

DEFINITIONS

Hereditary Angioedema (HAE) – a rare disorder characterized by recurrent attacks of swelling that may involve the peripheral extremities, abdomen, genitalia, face, oropharynx, or larynx due to low levels of endogenous or functional C1 inhibitor.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes

appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, C1 Esterase Inhibitor [human] (Berinert), ecallantide (Kalbitor), icatibant (Firazyr), and C1 Esterase Inhibitor [recombinant] (Ruconest) are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Berinert are subject to the preferred medical drug list program. This program applies to the hereditary angioedema products specified in this policy. Coverage for the targeted 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 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

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

Requests for Berinert must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION CRITERIA (*Use for Berinert Requests*)

Coverage for the targeted 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 targeted 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.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed below:

- Must be prescribed for the treatment of acute HAE attacks
- Must be prescribed by or under the direction of a HAE specialist. A HAE specialist is defined as an allergist/immunologist who demonstrates clinical expertise in HAE through research, publication, referrals/consults.
- Must have a diagnosis of HAE confirmed by all of the following laboratory values on two separate instances (copy of laboratory reports required, must include reference ranges):
    - Low C4 complement level (mg/dL)
    - Normal C1q complement component level (mg/dL)
        - C1q complement component level is not required for patients under the age of 18 OR patients whose symptoms began before age 18
- Either of the following:
    - Low C1 esterase inhibitor antigenic level (mg/dL)
    - Low C1 esterase inhibitor functional level (percent)
- Must have received at least one dose of requested product as treatment for acute HAE attack in the past. Chart documentation indicating patient response and ability to tolerate medication is required.
- Must meet the following age requirements:
    - Berinert- 2 years and older
    - Kalbitor- 12 years and older

- FIrazyr- 18 years and older
- Ruconest- 13 years and older

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	1 fill
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria update	*10/16, 12/16*
Preferred Product Update (effective 4/1/18)	*02/18*