Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Cinryze (C1 Inhibitor [human])***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***March 2009 (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 Cinryze (C1 Inhibitor [human]).

Cinryze (C1 Inhibitor [human]) is indicated for routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE.

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.

Hereditary Angioedema Specialist – an allergist/immunologist who demonstrates clinical expertise in HAE through research, publication, referrals/consults.

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

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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 drug, Cinryze (C1 Inhibitor [human]), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or under the direction of a HAE specialist
- Must be age 9 years or older
- Must be used as prophylactic therapy for the prevention of HAE attacks
- Must have a diagnosis of HAE confirmed by the following laboratory values on two separate instances (copy of laboratory reports required, must include reference ranges):
    - Low C4 complement level (mg/dL) AND
    - Normal C1q complement component level (mg/dL) AND
        - C1q complement component level is not required for patients under the age of 18 OR patients whose symptoms began before age 18
    - Low C1 esterase inhibitor antigenic level (mg/dL) OR
    - Low C1 esterase inhibitor functional level (percent)
- Must be a candidate for HAE prophylaxis therapy, demonstrating at least one of the following (chart documentation of each attack is required):
    - History of frequent HAE attacks defined as two or more HAE attacks per month
    - History of severe HAE attacks defined as one or more abdominal attacks in the past 12 months
    - History of any attack of the respiratory tract which compromised the airway
- Must have had a trial and failure, intolerance, or contraindication to an attenuated androgen (e.g., danazol, stanozolol, oxandrolone)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical

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Necessity for continuation of therapy. Authorization may be extended at one 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	Up to 4 months
Reauthorization	Up to 1 year

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

REFERENCES

1. Cinryze [Package Insert]. Exton, PA: ViroPharma, Inc.; October 2008
2. Gompels MM, Lock RJ, Abinun M et al. C1 inhibitor deficiency: consensus document. *Clinical and Experimental Immunology* 2005; 139:379-394
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8. Craig T, Reidl M, Dykewicz MS, et al. When is prophylaxis for hereditary angioedema necessary? *Ann Allergy Asthma Immunol* 2009;102:366-372

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

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Annual review	*02/17, 02/18*

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