Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.501	**Effective Date: 01/01/2020** **Revision Date: 07/2020**
Policy Name: Hereditary Angioedema Treatments	

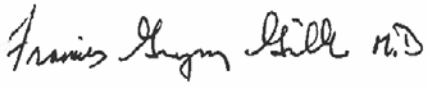
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q3 2020 annual review: no changes.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Hereditary Angioedema Treatments

Reference Number: PHW.PDL.501
Effective Date: 01/01/2020
Last Review Date: 07/2020

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Hereditary Angioedema Treatments are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Hereditary Angioedema (HAE) Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hereditary Angioedema (HAE) Agents that meet any of the following conditions must be prior authorized:

1. A prescription for a preferred or non-preferred HAE Agent.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an HAE Agent, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Has a diagnosis of hereditary angioedema (HAE) by an allergist/immunologist that is confirmed by all of the following:

   a. Low C4 complement level (mg/dL)
   b. Low C1 esterase inhibitor antigenic level (mg/dL) OR functional level (<65%)

   AND

2. Is not taking estrogen or an ACE inhibitor

   AND

3. Is being prescribed the HAE agent by an allergist/immunologist

   AND

4. If prescribed a human C1 esterase inhibitor:

   a. Was tested for hepatitis B, hepatitis C and HIV

AND

b. Received vaccination for hepatitis B

AND

5. If prescribed a C1 esterase inhibitor for prophylaxis, has a documented history of more than one HAE attack per month requiring acute treatment in the hospital emergency department (ED) setting

AND

6. For a non-preferred HAE agent:

   a. Has a documented history of therapeutic failure, contraindication or intolerance to the preferred HAE Agents

   OR

   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred HAE Agent

OR

7. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR AN HAE AGENT: Requests for prior authorization of renewals of prescriptions for an HAE agent that were previously approved will take into account whether the recipient:

1. Is being prescribed the HAE agent by an allergist/immunologist

AND

2. Had annual testing for hepatitis B, hepatitis C and HIV

AND

3. If prescribed a C1 esterase inhibitor for prophylaxis, has a documented reduction in the number and/or severity of HAE attacks

OR

4. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for an HAE Agent. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. **Approval Duration:**

Berinert, Ruconest, Firazyr, Kalbitor	**Acute attacks**	**6 months**
Cinryze, Haegarda	**Long-term prophylaxis**	**12 months**
	Short-term prophylaxis	**2 doses per procedure**
Takhzyro	**Long-term prophylaxis**	**New request: 6 months** **Renewal request: 12 months**

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020