UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Haegarda

Program	Prior Authorization
Medication	Haegarda® (C1 esterase inhibitor Subcutaneous, human)
Markets in Scope	Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	7/2017
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

Haegarda is a plasma-derived C1 esterase inhibitor subcutaneous (human) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.[1]

2. Coverage Criteria:

A. Initial Authorization

1. **Haegarda** will be approved based on **all** of the following criteria:

   a. Diagnosis of hereditary angioedema (HAE) as confirmed by **one** of the following:

      (1) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by **one** of the following (per laboratory standard):
      (a) C1-INH antigenic level below the lower limit of normal
      (b) C1-INH functional level below the lower limit of normal

-OR-

      (2) HAE with normal C1 inhibitor levels and **one** of the following:
      (a) Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
      (b) Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

-AND-

b. **All** of the following**:**

(1) Prescribed for the prophylaxis of HAE attacks

-AND-

(2) Not used in combination with other approved C1 esterase inhibitors indicated for prophylaxis against HAE attacks (e.g., Cinryze)

-AND-

(3) Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Haegarda

-AND-

c. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

Authorization of therapy will be issued for 12 months.

B. Reauthorization

1. **Haegarda** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response, defined as a clinically significant reduction in the rate and/or number of HAE attacks, while on Haegarda therapy

-AND-

b. Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Haegarda therapy

-AND-

c. **Both** of the following:

(1) Prescribed for the prophylaxis of HAE attacks

-AND-

(2) Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Takhzyro)

-AND-

d. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

Authorization of therapy will be issued for 12 months.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Haegarda [package insert]. Kankakee, IL: CSL Behring LLC.; October 2017.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10.
3. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2020.

Program	Prior Authorization - Haegarda (C1 esterase inhibitor subcutaneous, human)
Change Control	
8/2017	New program.
7/2018	Updated diagnosis criteria and added prescriber requirement and attestation to align with Employer and Individual's Medical Necessity Program for Haegarda. Updated references.
7/2019	Annual review. Added reauthorization criteria.
7/2020	Annual review. Aligned criteria with acute and prophylactic therapies. Added Additional Clinical Programs section. Updated references.