UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Berinert

Program	Prior Authorization
Medication	Berinert® (C1 esterase inhibitor, human)
Markets in Scope	Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

Berinert® is a plasma-derived C1 esterase inhibitor (human) indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) in adult and pediatric patients. The safety and efficacy of Berinert for prophylactic therapy has not been established.[1]

2. Coverage Criteria:

A. Initial Authorization:

1. **Berinert** 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. **Both** of the following:

(1) Prescribed for the treatment of acute HAE attacks

-AND-

(2) Not used in combination with other approved treatments for acute HAE attacks (e.g. Firazyr, Ruconest)

-AND-

c. **<u>One</u>** of the following**:**

(1) Submission of medical records documenting a history of failure, contraindication, or intolerance to Ruconest (C1 esterase inhibitor [recombinant])

-OR-

(2) Patient is currently on Berinert therapy

-AND-

d. Prescribed by **<u>one</u>** of the following:

(1) Immunologist
(2) Allergist

Authorization of therapy will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Berinert** will be approved based on **<u>all</u>** of the following criteria:

a. Documentation of positive clinical response

-AND-

b. **Both** of the following:

(1) Prescribed for the acute treatment of HAE attacks

-AND-

(2) Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Firazyr, Ruconest)

-AND-

c. 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. Berinert [package insert]. King of Prussia, PA: CSL Behring LLC.; April 2019.
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 –Berinert (C1 esterase inhibitor, human)
Change Control	

Date	Change
3/2013	New pharmacy/medical guideline
9/2014	Cinryze: Changed prophylaxis “of” to “against” HAE attacks, changed history of failure, contraindication, or intolerance of “alkylated androgen (eg, danazol)” to “17-alpha alkylated androgen (eg, danazol, oxandrolone) or Antifibrinolytics (eg, aminocaproic acid, tranexamic acid)”, and added continuation of prior therapy for patients who are being treated prophylactically. For the off-label treatment indication, added “Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, Kalbitor or Ruconest).” Berinert: Added “Not used in combination with other approved treatments for acute HAE attacks (e.g. Firzayr, Kalbitor or Ruconest).” Added new criteria for Ruconest, a newly approved C1 esterase inhibitor (recombinant), mirroring Firazyr and Berinert, with an authorization duration of 12 months: • Diagnosis of HAE • For the treatment of acute HAE attacks • Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firzayr, or Kalbitor) • Prescribed by an immunologist, allergist, or rheumatologist
7/2016	Updated clinical criteria to align with Employer and Individual. Cinryze, Berinert, Ruconest separated into individual policies to align with Employer and Individual. Updated policy to new template.
7/2017	Updated background and references.
7/2018	Annual review. No changes to criteria. Updated reference.
7/2019	Annual review. No changes to criteria.
7/2020	Updated clinical criteria: Added that diagnosis must be confirmed by certain tests; added step thru Ruconest; added prescriber requirement. Added reauthorization criteria Added Additional Clinical Rules Section. Updated references.