

Clinical Pharmacy Program Guidelines for Berinert

Program	Prior Authorization
Medication	Berinert [®] (C1 esterase inhibitor, human)
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

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:

<p>A. Berinert will be approved based on all of the following criteria:</p> <ol style="list-style-type: none"> 1. Diagnosis of hereditary angioedema (HAE) <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> 2. For the treatment of acute HAE attacks <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> 3. Not used in combination with other approved treatments for acute HAE attacks (e.g. Firazyr, Kalbitor or Ruconest) <p>Authorization of therapy will be issued for 12 months.</p>

3. References:

1. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September 2016.

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Change Control	
Date	Change
3/2013	New pharmacy/medical guideline
9/2014	<p>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, Firzayr, Kalbitor or Ruconest).”</p> <p>Berinert: Added “Not used in combination with other approved treatments for acute HAE attacks (e.g. Firzayr, Kalbitor or Ruconest).”</p> <p>Added new criteria for Ruconest, a newly approved C1 esterase inhibitor (recombinant), mirroring Firzayr and Berinert, with an authorization duration of 12 months:</p> <ul style="list-style-type: none"> • 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.