

Berinert® (C1 esterase inhibitor [Human])



When requesting Berinert® (C1 esterase inhibitor [Human]), the individual requiring treatment must be diagnosed with an FDA-approved indication use and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication¹

- Berinert is indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adults and pediatric patients.

Approved Off-label Compendial uses

- None

Coverage Guidelines

- Has a diagnosis of hereditary angioedema (HAE) confirmed by C4 and C1 inhibitor laboratory testing (i.e. low C4 levels, low C1 inhibitor antigenic protein levels, low C1 inhibitor functional levels)³
- Request is for the treatment of acute HAE attacks^{1,2}
- Member does not have a history of life-threatening immediate hypersensitivity reactions to C1 esterase inhibitor preparations including anaphylaxis (e.g., Cinryze, Ruconest)¹
- Berinert will not be used in combination with another agent for treating acute attacks of HAE (e.g., Firazyr, Kalbitor, Ruconest)^{3,4}

Additional Information for Prescribers¹

- Hypersensitivity reactions may occur. Epinephrine should be immediately available to treat any acute severe hypersensitivity reactions following discontinuation of administration
- Serious arterial and venous thromboembolic (TE) events have been reported following Berinert administration. Risk factors may include the presence of an indwelling venous catheter/access device, prior history of thrombosis, underlying atherosclerosis, use of oral contraceptives or certain androgens, morbid obesity, and immobility. Patients with known risk factors should be monitored for TE events during and after Berinert administration.
- Berinert is made from human plasma and may contain infectious agents, e.g., viruses the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt- Jakob disease (CJD) agent.

References

1. Berinert prescribing information. Kankakee, IL; CSL Behring LLC. September 2016. Available at <http://www.berinert.com/prescribing-information.aspx> . Accessed January 06, 2017.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed January 06, 2017. <http://www.micromedexsolutions.com/home/dispatch>
3. Craig, T, Pursun E, Bork, K, et al. WAO Guideline for the Management of Hereditary Angioedema. *World Allergy Organization Journal*. 2012; 5:182–199.
4. Zuraw, B, Banerji, A, Bernstein J, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 Recommendations for the Management of Hereditary Angioedema Due to C1 Inhibitor Deficiency. *American Academy of Allergy, Asthma & Immunology*. 2013;1:458-67.