



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Beriner is a human plasma derived C1-esterase inhibitor for the treatment of acute attacks in adult and pediatric patients with hereditary angioedema (HAE). Hereditary angioedema is caused by having insufficient amounts of a plasma protein called C1-esterase inhibitor. People with HAE can develop rapid swelling of the hands, feet, limbs, face, intestinal tract, or airway. These acute attacks of swelling can occur spontaneously, or can be triggered by stress, surgery or infection. Swelling of the airway is potentially fatal without immediate treatment. Beriner is intended to restore the level of functional C1-esterase inhibitor in a patient's plasma, thereby treating the acute attack of swelling (1).

### **Regulatory Status**

FDA-approved indication: Beriner 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 (1).

Hypersensitivity reactions may occur. Epinephrine should be immediately available to treat any acute severe hypersensitivity reactions following discontinuation of administration (1).

Thrombotic events have been reported at the recommended dose of C1 Esterase Inhibitor (Human) products, including Beriner, following treatment of HAE. Monitor closely patients with known risk factors for thrombotic events (1).

Beriner is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent (1).

Following self-administration of Beriner for laryngeal attacks, advise patients to immediately seek medical attention (1).

The safety and efficacy of Beriner for prophylactic therapy have not been established (1).

The safety and efficacy of Beriner in pediatric patients less than 5 years of age have not been established (1).



**BlueCross  
BlueShield**

Federal Employee Program.

**BERINERT**  
(C1 esterase inhibitor [human])

**Summary**

Berinerter is a C1 esterase inhibitor (plasma derived) indicated for the treatment of acute attacks in adult and pediatric patients with hereditary angioedema (HAE). HAE symptoms include episodes of edema (swelling) in various body parts including the hands, feet, face, and airway. HAE is caused by mutations to C1-esterase-inhibitor (C1-INH). Serious arterial and venous thromboembolic (TE) events have been reported at the recommended dose of plasma derived C1 esterase inhibitor products in patients with risk factors (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Berinerter while maintaining optimal therapeutic outcomes.

**References**

1. Berinerter [package insert]. Kankakee, IL. CSL Behring LLC. September 2021.