



**BlueCross  
BlueShield**

Federal Employee Program.

**KALBITOR**  
(ecallantide)

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

### **Background**

Kalbitor (ecallantide) is a human plasma kallikrein inhibitor for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Hereditary angioedema, which 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. Kalbitor 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: Kalbitor is a plasma kallikrein inhibitor indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years of age and older (1).

Kalbitor includes a boxed warning of serious hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred in 4% of treated patients. Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema (1).

The safety and efficacy of Kalbitor in pediatric patients less than 12 years of age have not been established (1).

### **Summary**

Kalbitor (ecallantide) is a plasma kallikrein inhibitor indicated for the treatment of acute attacks in adult and adolescent 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). The safety and efficacy of Kalbitor in pediatric patients less than 12 years of age have not been established (1).

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

### **References**



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1. Kalbitor [package insert]. Lexington, MA : Dyax Corp.; November 2021.