

**ADAKVEO  
(crizanlizumab-tmca)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Adakveo (crizanlizumab-tmca) is a first-in-class, humanized IgG2 kappa monoclonal antibody that binds to P-selectin and blocks interactions with its ligands including P-selectin glycoprotein ligand 1. Binding P-selectin on the surface of the activated endothelium and platelets blocks interactions between endothelial cells, platelets, red blood cells, and leukocytes. It is indicated to reduce the frequency of vasoocclusive crises in patients with sickle cell disease (SCD). Sickle cell disease is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent, or "sickle," shape). This restricts the flow in blood vessels and limits oxygen delivery to the body's tissues, leading to severe pain and organ damage (1).

Two effective disease-modifying therapies for SCD (hydroxyurea and chronic transfusion) are potentially widely available but remain underutilized. These are the only currently proven disease-modifying treatments for people with SCD. Both therapies are used in primary and secondary stroke prevention. Although neither has been shown to prevent all SCD-related organ damage, these treatment modalities can improve the quality of life for individuals with SCD. Currently, the only cure for sickle cell disease is a blood and bone marrow transplant though transplant is not for everyone (2).

**Regulatory Status**

FDA-approved indication: Adakveo is a selectin blocker indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease (1).

Infusion-related reactions have occurred in patients treated with Adakveo. Patients should be monitored for signs and symptoms of infusion-related reactions, including fever, chills, nausea, vomiting, fatigue, dizziness, pruritus, urticarial, sweating, shortness of breath, or wheezing. Adakveo should be discontinued for severe reactions (1).

Adakveo should be prepared and administered by a healthcare professional (1).

The safety and effectiveness of Adakveo in pediatric patients less than 16 years of age have not been established (1).



**BlueCross  
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### **Summary**

Adakveo is used in the treatment for patients with sickle cell disease to reduce severe complications associated with the blood disorder. Sickle cell disease is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent, or "sickle," shape). This restricts the flow in blood vessels and limits oxygen delivery to the body's tissues, leading to severe pain and organ damage. The safety and effectiveness of Adakveo in pediatric patients less than 16 years of age have not been established (1).

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

### **References**

1. Adakveo [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. Gibbons G, Shurin S, et al. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report (EPR), 2014. U.S. Department of Health and Human Services National Institutes of Health