BlueCross BlueShield
Federal Employee Program

ENJAYMO
(sutimlimab-jome)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Enjaymo (sutimlimab-jome) is an immunoglobulin G (IgG) monoclonal antibody (mAb) that inhibits the classical complement pathway by binding to complement protein component 1,s (C1s). In cold agglutinin disease (CAD), a component of the immune system (the classical complement pathway) marks red blood cells for hemolysis. In patients with CAD, the bone marrow cannot compensate for the loss of blood cells due to hemolysis, ultimately leading to anemia and its symptoms (1).

Regulatory Status

FDA-approved indication: Enjaymo is a classical complement inhibitor indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD) (1).

Enjaymo can increase the risk for serious infection. Patients should be vaccinated against encapsulated bacteria at least two weeks prior to starting treatment. Patients should be monitored for signs and symptoms of infections (1).

Infusion-related reactions and autoimmune diseases have also occurred. Patients should be monitored for the signs and symptoms of infusion related reactions and autoimmune diseases. If either condition occurs while being treated with Enjaymo, they should be managed as medically appropriate (1).

Patients that discontinue or have an interruption in treatment with Enjaymo can experience recurrent hemolysis. Patients should be monitored for the signs and symptoms of hemolysis if treatment with Enjaymo is interrupted (1).

The safety and effectiveness of Enjaymo in pediatric patients less than 18 years of age have not been established (1).

Summary

Enjaymo is a classical complement inhibitor indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD). Enjaymo has warnings for increased risk of serious infections, autoimmune disease, infusion-related reactions, and recurrent hemolysis after treatment

discontinuation. The safety and effectiveness of Enjaymo in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Enjaymo [package insert]. Waltham, MA: Bioverativ USA Inc.; February 2024.