

Enjaymo® (sutimlimab-jome)

When requesting Enjaymo (sutimlimab-jome), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication

Enjaymo is indicated for the treatment of individuals with cold agglutinin disease.

Coverage Guidelines

Cold Agglutinin Disease

The individual must meet all of the following criteria for approval.

- A) Patient is ≥ 18 years of age;
- B) Patient weighs ≥ 39 kg;
- C) Patient has a history of at least one sign or symptom associated with cold agglutinin disease;
Note: Examples include symptomatic anemia (e.g., anemia associated with fatigue, weakness, shortness of breath, heart palpitations, lightheadedness, chest pain), acrocyanosis, Raynaud's syndrome, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event (e.g., thrombosis).
- D) The patient has evidence of chronic hemolysis;
- E) Patient meets the following diagnostic criteria;
 - a. Direct antibody test strongly positive for C3d and negative or only weakly positive for immunoglobulin G;
 - b. Cold agglutinin antibody titer ≥ 64 at 4°C (approximately 40°F);
- F) At baseline (prior to the initiation of Enjaymo), patient meets both of the following;
 - a. Hemoglobin ≤ 10 g/dL;
 - b. Total bilirubin above the upper limit of normal, based on the reference range for the reporting laboratory;
- G) Secondary causes of cold agglutinin syndrome have been excluded;
Note: Examples of secondary causes of cold agglutinin syndrome include infection, rheumatologic diseases, and active hematologic malignancies.
- H) Enjaymo is prescribed by or in consultation with a hematologist.

Approval duration: 1 year

Dosing Recommendations

Patient weighs ≥ 75 kg: Approve 7,500 mg intravenously not more frequently than once weekly.
Patient weighs < 75 kg: Approve 6,500 mg intravenously not more frequently than once weekly

References

1. Enjaymo™ intravenous infusion [prescribing information]. Waltham, MA: Bioverativ/Sanofi; February 2022.
2. Berentsen S, Röth A, Randen U, et al. Cold agglutinin disease: current challenges and future prospects. *J Blood Med*. 2019;10:93-103.
3. Berentsen S. How I treat cold agglutinin disease. *Blood*. 2021;137(10):1295-1303.
4. Swiecicki PL, Hegerova LT, Gertz MA. Cold agglutinin disease. *Blood*. 2013;122(7):1114-1121.
5. Röth A, Barcellini W, D'Sa S, et al. Sutimlimab in cold agglutinin disease. *N Engl J Med*. 2021 Apr 8;384(14):1323-1334.
6. Röth A, Berentsen S, Barcellini W, et al. Inhibition of complement C1s by sutimlimab in patients with cold agglutinin disease (CAD): efficacy and safety results from the randomized, placebo-controlled phase 3 CADENZA study. *Blood*. 2021;138 (Suppl 1):349.
7. Jäger U, Barcellini W, Broome CM, et al. Diagnosis and treatment of autoimmune hemolytic anemia in adults: recommendations from the First International Consensus Meeting. *Blood Rev*. 2020 May;41:100648.