

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 hemolysis in adults with cold agglutinin disease.

Coverage Guidelines

Cold Agglutinin Disease

The individual must meet **ALL** of the following criteria for approval.

- Is ≥ 18 years of age;
- Weighs ≥ 39 kg;
- 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).
- Has evidence of chronic hemolysis;
- Meets the following diagnostic criteria:
 - Direct antibody test strongly positive for C3d and negative or only weakly positive for immunoglobulin G;
 - Cold agglutinin antibody titer ≥ 64 at 4°C (approximately 40°F);
- At baseline (prior to the initiation of Enjaymo), patient meets both of the following:
 - Hemoglobin ≤ 10 g/dL;
 - Total bilirubin above the upper limit of normal, based on the reference range for the reporting laboratory;
- 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.
- Enjaymo is prescribed by or in consultation with a hematologist.

Approval duration: 12 months

Dosing Recommendations

Patient weighs 75 kg or more: Administer 7,500 mg intravenously weekly for the first two weeks, then every two weeks thereafter.

Patient weighs 39 kg to less than 75 kg: Administer 6,500 mg intravenously weekly for the first two weeks, then every two weeks thereafter.

References

1. Enjaymo™ intravenous infusion [prescribing information]. Waltham, MA: Bioverativ/Sanofi; November 2024.
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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.
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7. Röth A, Barcellini W, D'Sa S, et al. Sustained inhibition of complement C1s with sutimlimab over 2 years in patients with cold agglutinin disease. *Am J Hematol*. 2023;98(8):1246-1253.
8. Röth A, Berentsen S, Barcellini W, D'Sa S, et al. Sutimlimab in patients with cold agglutinin disease: results of the randomized placebo-controlled phase 3 CADENZA trial. *Blood*. 2022;140(9):980-991.
9. 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.
10. Barcellini W, Fattizzo B. The evolving management algorithm for a patient with newly diagnosed cold agglutinin disease. *Expert Rev Hematol*. 2024;17(7):287-294.