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; AND
  - 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; AND
  - 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; February 2024.
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, Broome CM, Barcellini W, et al. Long-term sutimlimab improves quality of life for patients with cold agglutinin disease: CARDINAL 2-year follow-up. *Blood Adv*. 2023;7(19):5890-5897.
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.