Enjaymo (sutimlimab-jome)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial Approval: 6 months Continuation approval: 1 year

Medications	Quantity Limit
Enjaymo (sutimlimab) 1100mg/22 mL vial	6 vials (6,600 mg total) per 2 weeks

For initiation of therapy, may approve up to 6 (6,600 mg) additional vials in the first 2 weeks of treatment for those weighing less than 75 kg or up to 7 (7,700 mg total) additional vials in the first 2 weeks for those weighing 75 kg or greater.
For maintenance treatment, those weighing 75 kg or greater may approve 1 additional vial (1,100 mg total) every 2 weeks (7 vials per 2 weeks).

APPROVAL CRITERIA

Initial requests for Enjaymo (sutimlimab-jome) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of cold agglutinin disease (CAD) defined as **ALL** of the following:
    A. The presence of chronic hemolysis; **AND**
    B. A positive polyspecific direct antiglobulin test result; **AND**
    C. A monospecific direct antiglobulin test result strongly positive for C3d; **AND**
    D. A cold agglutinin titer of 1:64 or higher measured at 4°C; **AND**
    E. A direct antiglobulin test result for IgG of 1+ or less; **AND**
    F. Presence of one or more symptoms associated with CAD (i.e. symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event); **AND**
III. Individual is using Enjaymo to decrease the need for red blood cell transfusions due to hemolysis with cold agglutin disease (CAD)

Continuation of use criteria for Enjaymo (sutimlimab-jome):

I. Individual has a diagnosis of Cold Agglutinin disease (CAD); **AND**
II. Individual has no evidence of unacceptable toxicity or disease progression while on current regimen; **AND**
III. Individual has had successful prior therapy for 6 months, with success defined as one of the following:

A. Hemoglobin (Hgb) mean change from baseline (baseline defined as the last Hgb value before administration of the first dose at initial therapy) increased greater than or equal to 2 g/dL; **OR**
B. Individual accomplished Hgb level greater than or equal to 12 g/dL at the treatment assessment endpoint; **OR**
C. Individual did not need additional blood transfusions from week 5 through week 26 of initial therapy.

Enjaymo (sutimlimab-jome) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 17, 2023.
6. Röth A, Barcellini W, D'Sa S, et al; Inhibition of Complement C1s with Sutimlimab in Patients with Cold Agglutinin Disease (CAD): Results from the Phase 3 Cardinal Study. *Blood*. 2019; 134 (Supplement_2): LBA–2. doi: https://doi.org/10.1182/blood-2019-132490 Available at https://ashpublications.org/blood/article/134/Supplement_2/LBA-2/428841/Inhibition-of-Complement-C1s-with-Sutimlimab-in .