Medical Drug Clinical Criteria

Subject:	Enjaymo (sutimlimab-jome)		
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Overview

This document addresses the use of Enjaymo (sutimlimab-jome). Enjaymo is an intravenous monoclonal antibody that selectively blocks the activity of C1s, which would in turn inhibit the classical complement pathway causing hemolysis in Cold Agglutinin Disease (CAD). CAD may be primary with an unknown cause or secondary due to infection or disease conditions. Severity of CAD ranges from compensated hemolysis without anemia to severe hemolytic anemia. Those CAD patients with severe hemolytic anemia may require transfusions for short or long periods of time. Additional therapies such as rituximab alone, or in combination with bendamustine, or fludarabine, are used as off-label agents to reduce antibody production in CAD.

Definitions and Measures

CAD: Cold Agglutinin Disease is a rare form of autoimmune hemolytic anemia, where the immune system erroneously destroys red blood cells, leading to anemia and other symptoms

Monoclonal antibody: A protein developed in the laboratory that can locate and bind to specific substances in the body and on the surface of cancer cells.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Enjaymo (sutimlimab-jome)

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 1.5 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.

Approval Durations:

Initial Approval: 6 months
Continuation approval: 1 year

Quantity Limits

Enjaymo (sutimlimab-jome) Quantity Limit

Drug	Limit
Enjaymo (sutimlimab-jome) 1,100mg/22 mL vial (50 mg/mL)	6 vials (6,600 mg total) per 2 weeks
Override Criteria	
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).	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1302	Injection, sutimlimab-jome, 10 mg [Enjaymo]

ICD-10 Diagnosis

D59.12	Cold autoimmune hemolytic anemia

Document History

Revised: 02/24/2023
Document History:

- 02/24/2023 – Annual Review: Revise criteria due to FDA label updates and for continuation of use. Add drug strength for the vial in the quantity limit. Coding Reviewed: No changes.
- 02/25/2022 – New clinical criteria document for Enjaymo. Coding Reviewed: Added HCPCS J3490, J3590, C9399, J9999. All diagnoses pend. Effective:7/1/2022 Added HCPCS C9094. Removed HCPCS C9399. Added ICD-10-CM D59.12. Removed All diagnoses pend. Effective 10/1/2022 Added HCPCS J1302. Removed J3490, J3590, J9999, C9094.

References

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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 .

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.