Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Sutimlimab-jome (Enjaymo®)	MP-RX-FP-141-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Sutimlimab-jome (Enjaymo®), an immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody approved by the Food and Drug Administration (FDA) for the treatment of hemolysis in adults with cold agglutinin disease (CAD).

Background Information

Sutimlimab 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.

Approved Indications

ENJAYMO is indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD).

Other Uses

None.

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

ICD-10	Description
D59.12	Cold autoimmune hemolytic anemia

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Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Sutimlimab-jome (Enjaymo®)

A. Criteria For Initial Approval

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 4oC; **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)

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Sutimlimab-jome (Enjaymo®) therapy medically necessary in members requesting reauthorization if the the following information is provided for reauthorization:

- A. Individual has a diagnosis of Cold Agglutinin disease (CAD); **AND**
- B. Individual has no evidence of unacceptable toxicity or disease progression while on current regimen; **AND**
- C. Individual has had successful prior therapy for 6 months, with success defined as one of the following:
  1. 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

  2. Individual accomplished Hgb level greater than or equal to 12 g/dL at the treatment assessment endpoint;

OR

3. Individual did not need additional blood transfusions from week 5 through week 26 of initial therapy.

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Enjaymo (sutimlimab-jome) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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Body Weight Range	Dose	Number of vials needed
Greater than or equal to 39 kg to less than 75 kg	6,500 mg	6
75 kg or greater	7,500 mg	7
Exceptions		
• Administer intravenously weekly for the first two weeks, with administration every two weeks thereafter. • Administer at the recommended dosage regimen time points, or within two days of these time points.		

Reference Information

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 . 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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption	N/A	6/28/2024

Revised: 01/26/2024