RX.PA.075.MPC Enjaymo (sutimlimab-jome intravenous infusion)

PURPOSE

The purpose of this policy is to define the prior authorization process for Enjaymo (sutimlimab-jome intravenous infusion).

Enjaymo, a classical complement inhibitor, is indicated for cold agglutinin disease, in adults to decrease the need for red blood cell (RBC) transfusion due to hemolysis.

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. Cold Agglutinin Disease:

- Member is ≥ 18 years of age; AND
- Member weighs ≥ 39 kg; AND
- Member has a history of at least one sign or symptom associated with cold agglutinin disease; AND
  - 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).
- According to the prescriber, the member has evidence of chronic hemolysis; AND
- Member 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); AND
- At baseline (prior to the initiation of Enjaymo), member 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; AND
- According to the prescriber, secondary causes of cold agglutinin syndrome have been excluded; AND
  - Note: Examples of secondary causes of cold agglutinin syndrome include infection, rheumatologic diseases, and active hematologic malignancies.
- Member has a documented history of at least one blood transfusion within the past 6 months
- Dose does not exceed FDA approved label dosing for indication

- Member will not receive Enjaymo in combination with a complement inhibitor (i.e. Soliris, Ultomiris, Empaveli)
- Member will not receive concomitant treatment with rituximab or rituximab-containing regimensEnjaymo is prescribed by or in consultation with a hematologist.

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Enjaymo will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria: All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon all of the following:

- MPC Renewal:
  - Chart documentation confirming positive response to therapy as evidenced by a documented improvement (e.g., improvement in hemoglobin levels- increase in hemoglobin > 2 g/dL, decreased markers of hemolysis [e.g., bilirubin, haptoglobin, lactate dehydrogenase [LDH], reticulocyte count], and a reduction in blood transfusions).
  - Member will not receive Enjaymo in combination with a complement inhibitor (i.e. Soliris, Ultomiris, Empaveli)
  - Enjaymo is prescribed by or in consultation with a hematologist.

- Renewal from Previous Insurer:
  - Members who have received prior approval (from insurer other than MPC) and have been taking Enjaymo, or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
  - Provider has a documented clinical response of the member's improvement on treatment from baseline.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	3 months
Reauthorization	1 year

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J1302	Injection, sutimlimab-jome, 10 mg
C9094	Injection, sutimlimab-jome, 10 mg

REFERENCES

1. Enjaymo™ intravenous infusion [prescribing information]. Waltham, MA: Bioverativ/Sanofi; February 2022.
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, Berentsen S, Barcellini W, et al. Inhibition of complement C1s by sutimlimab in members with cold agglutinin disease (CAD): efficacy and safety results from the randomized, placebo-controlled phase 3 CADENZA study. *Blood.* 2021;138 (Suppl 1):349.
7. 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.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2026*
Annual Review	*02/2025*
Annual policy review. Update to reauthorization criteria for non-MPC renewals	*02/2024*
New Policy	*08/2023*