Reference number(s)
5201-A

STANDARD MEDICARE PART B MANAGEMENT

ENJAYMO (sutimlimab-jome)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Enjaymo is indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD).

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. For initial requests: chart notes, medical records or test results documenting:
   1. Lactate dehydrogenase (LDH) level above the upper limit of normal and haptoglobin level below the lower limit of normal
   2. Positive polyspecific direct antiglobulin test (DAT) result
   3. Monospecific DAT result strongly positive for C3d
   4. Cold agglutinin titer of 1:64 or higher measured at 4°C
   5. DAT result for IgG of 1+ or less
   6. Secondary CAD has been ruled out (e.g., cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy)
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. CRITERIA FOR INITIAL APPROVAL

Cold Agglutinin Disease (CAD)
Authorization of 6 months may be granted for the treatment of cold agglutinin disease (CAD) when all of the following criteria are met:
A. Confirmed diagnosis of primary cold agglutinin disease (CAD) based on all of the following:
   1. Evidence of hemolysis as indicated by both of the following:

i. Lactate dehydrogenase (LDH) level above the upper limit of normal
ii. Haptoglobin level below the lower limit of normal

2. Positive polyspecific direct antiglobulin test (DAT) result
3. Monospecific DAT result strongly positive for C3d
4. Cold agglutinin titer of 1:64 or higher measured at 4°C
5. DAT result for IgG of 1+ or less

B. Secondary CAD has been ruled out (e.g., cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy)

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Enjaymo.
B. Enjaymo is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen, and
   2. No evidence of disease progression while on the current regimen, and
   3. Positive response to therapy (e.g., improvement in hemoglobin levels, improvement in markers of hemolysis [e.g., bilirubin, haptoglobin, lactate dehydrogenase [LDH], reticulocyte count], a reduction in blood transfusions).

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Enjaymo.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Enjaymo are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

1. Enjaymo [package insert]. Waltham, MA: Bioverativ USA Inc.; January 2023.

2. Röth A, Barcellini W, D'Sa S, Miyakawa Y, Broome CM, Michel M, Kuter DJ, Jilma B, Tvedt THA, Fruebis J, et al. Sutimlimab in cold agglutinin disease. N Engl J Med. 2021;384(14):1323–34.
3. 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;41:100648.