Enjaymo (sutimlimab-jome)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Enjaymo (sutimlimab-jome) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Enjaymo is indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

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.

Criteria for Initial Approval

Enjaymo (sutimlimab-jome) may be considered **medically necessary** 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. History of at least one blood transfusion within the past 6 months
C. Secondary CAD has been ruled out (e.g., cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy)
D. Patient has had an inadequate response to rituximab or has a contraindication or medically justifiable reason that precludes the use of rituximab.

Approval is for **6 months.**

Continuation of Therapy

Enjaymo (sutimlimab-jome) may be considered **medically necessary** for the continued treatment of cold agglutinin disease (CAD) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and member demonstrates a positive response to therapy (e.g., improvement in hemoglobin levels, markers of hemolysis [e.g., bilirubin, haptoglobin, lactate dehydrogenase [LDH], reticulocyte count], and a reduction in blood transfusions).

Approval is for **12 months.**

Enjaymo (sutimlimab-jome) considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Medication	FDA-Recommended Dosing
Enjaymo (sutimlimab-jome) 1,100 mg/22 mL (50 mg/mL) single-dose vial	• Weight-based dosage weekly for two weeks then every two weeks: o For patients weighing 39 kg to less than 75 kg: 6,500 mg by intravenous infusion. o For patients weighing 75 kg or more: 7,500 mg by intravenous infusion.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9094 Injection, sutimlimab-jome, 10 mg (effective 7-1-22, deleted 10/1/22)
- J1302 Injection, sutimlimab-jome, 10 mg (effective 10-1-22)

REFERENCES

- Enjaymo [package insert]. Waltham, MA: Bioverativ USA Inc Inc.; February 2022.
- 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.
- 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.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.58
Reviewed: April 2022
Revised:
Current Effective Date: July 1, 2022