POLICY Document for ENJAYMO (sutimlimab-jome)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Administration of Intravenous Enjaymo

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Enjaymo in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Enjaymo in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction to the drug that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
C. The member has severe venous access issues that require the use of special interventions only available in the outpatient hospital setting.
D. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
E. Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
F. The member is less than 14 years of age.

For situations where administration of Enjaymo does not meet the criteria for outpatient hospital infusion, coverage for Enjaymo is provided when administered in alternative sites such as physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion

B. Medical records supporting the member is medically unstable
C. Medical records supporting the member has severe venous access issues that requires specialized interventions only available in the outpatient hospital setting
D. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
E. Records supporting alternative infusion sites are greater than 30 miles from the member's home.
F. Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

SPECIALTY GUIDELINE 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 are considered experimental/investigational and not medically necessary.

II. 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.

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

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization 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, improvement in markers of hemolysis [e.g., bilirubin, haptoglobin, lactate dehydrogenase [LDH], reticulocyte count], a reduction in blood transfusions).

REFERENCES

SECTION 1

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

SECTION 2

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