sutimlimab-jome (Enjaymo)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: An immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody
HCPCS:
J1302:Injection, sutimlimab-jome, 10 mg
How Supplied:
1,100 mg/22 mL (50 mg/mL) in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Primary Cold Agglutinin Disease (CAD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF ENJAYMO IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy (allowed for the first 3 infusions) with Enjaymo or is being re-initiated on Enjaymo after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Enjaymo based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Enjaymo based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Primary Cold Agglutinin Disease (CAD)

Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a hematologist
2. Confirmed diagnosis of CAD based on ALL of the following:
   a. Presence of chronic hemolytic anemia (e.g. increased lactated dehydrogenase (LDH), decreased haptoglobin, increased indirect bilirubin, increased reticulocyte count
   b. Positive polyspecific direct antiglobin test (DAT)
   c. Positive monospecific DAT specific for C3d
   d. DAT for IgG of ≤ 1+
   e. Cold agglutinin titer of 1:64 or higher measured at 4°C
3. Current Hgb level is ≤10 mg/dL
4. Not being used in combination with a complement inhibitor (e.g., Soliris, Ultomiris, Empaveli)

Covered Doses:

39 kg to less than 75 kg	6,500 mg given intravenously weekly for 2 weeks followed by 6,500 mg every two weeks
75 kg or more	7,500 mg given intravenously weekly for 2 weeks followed by 7,500 mg every two weeks

Coverage Period:

Initial authorization: 26 weeks

Reauthorization: Yearly if meets BOTH of the following:

1. Meets ONE of the following:
   a. Increase in HgB ≥1.5 mg/dL over baseline
   b. Reduction in transfusion burden
   c. Reduction in markers of hemolysis
   d. Improvement in anemia-related symptoms
2. Not being used in combination with a complement inhibitor (e.g., Soliris, Ultormiris, Empaveli)

ICD-10:
D59.12

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Enjaymo (sutimlimab-jome) Prescribing Information. Bioverativ USA Inc., Waltham, MA: 02/2024.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change to policy following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee