Sutimlimab-jome (Enjaymo™)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration* [*Prior authorization required – see section (1)] HCPCS: J1302 per 10 mg

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

- Cold agglutinin disease (CAD), primary

AHFS therapeutic class: Blood Products/Modifiers/Volume Expanders

Mechanism of action: An immunoglobulin G subclass 4 (IgG4) monoclonal antibody that inhibits the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of RBCs, resulting in inhibition of hemolysis in patients with CAD.

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****
AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, Medi-Cal, and when applicable, ASO/Shared Advantage/HMO (non-direct contract),** 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 ****
AAAAI Guidelines 2011, 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 receiving initial treatment (allowed for the first 3 infusions) of 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.*

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

2. **Patient has experienced a previous severe adverse event to Enjaymo based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events to 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for sutimlimab-jome (Enjaymo™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Cold agglutinin disease (CAD), primary

1. ***Effective 7/31/2023 an after***: Prescribed by or in consultation with a hematologist, **AND**
2. ***Effective 7/31/2023 an after***: 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, AND
    b. Positive polyspecific direct antiglobin test (DAT), AND
    c. Positive monospecific DAT specific for C3d, AND
    d. DAT for IgG of ≤ 1+, AND
    e. Cold agglutinin titer of 1:64 or higher measured at 4**°C**

    AND
3. Current Hgb level is ≤10 mg/dL, **AND**
4. ***Effective 7/31/2023 an after***: 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 IV weekly for 2 weeks followed by 6,500 mg IV every two weeks
75 kg or more	7,500 mg IV weekly for 2 weeks followed by 7,500 mg IV every two weeks

Coverage Period

Initial authorization: 26 weeks

Reauthorization: Indefinite if the following is met

1. One of the following:
    a. Increase in HgB ≥1.5 mg/dL over baseline, or
    b. Reduction in transfusion burden, or
    c. Reduction in markers of hemolysis, or
    d. Improvement in anemia-related symptoms

    AND
2. ***Effective 7/31/2023 an after***: Not being used in combination with a complement inhibitor (e.g. Soliris, Ultormiris, Empaveli)

ICD-10:
D59.12

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for sutimlimab-jome (Enjaymo™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 1,100 mg/22 mL (50 mg/mL) in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Enjaymo™ (sutimlimab-jome) [Prescribing information]. Bioverativ USA Inc., Waltham, MA. 02/2022.
- Roth A MD, Barcellini W MD, et al. Sutimlimab in Cold Agglutinin Disease. New England Journal of Medicine 2021;384:1323-34.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- Section (2): Primary cold agglutinin disease (CAD) – Effective 7/31/2023 and after, will add requirement for confirmation of diagnosis of CAD, hematologist specialist, and management of combination use with competing complement inhibitors.

  Rationale: *Phase III cardinal pivotal trial*

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee