Medical Policy:

Enjaymo™ (sutimlimab-jome) Intravenous Infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.352	April 4, 2025	May 12, 2022

Definitions:

ENJAYMO (sutimlimab-jome) is indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD). Sutimlimab is a humanized immunoglobulin G (IgG4) monoclonal antibody which targets and inhibits complement. Sutimlimab inhibits the classical complement pathway by specifically binding to the complement protein component 1, s subcomponent (C1s), which is a serine protease that cleaves C4. Inhibition of the classical complement pathway at the C1s level prevents deposition of complement opsonins on RBC surfaces, resulting in inhibition of hemolysis in cold agglutinin disease.

Length of Authorization

Coverage will be provided for 6 months and can be renewed

Dosing Limits [Medical Benefit]

Administer sutimlimab at the recommended dosage regimen time points, or within 2 days of these time points.

- 39 kg to <75 kg: **IV:** 6.5 g once weekly for 2 weeks (on days 0 and 7), followed with 6.5 g once every 2 weeks thereafter, beginning on day 21.

- ≥75 kg: **IV:** 7.5 g once weekly for 2 weeks (on days 0 and 7), followed with 7.5 g once every 2 weeks thereafter, beginning on day 21.
- **Max Units (per dose and over time) [HCPCS Unit]:**
  750 billable units (7500 mg) weekly for two doses then every 2 weeks thereafter

Indication	Dose
Cold-Agglutinin Disease (CAD)	Administer intravenously weekly for the first two weeks, with administration every two weeks thereafter based on the following weight-based dosing.: – 39 kg to less than 75 kg: 6,500 mg – 75 kg or more: 7,500 mg *Note: Doses should be administered at the above intervals, or within two days of these time points.*

Guideline

INITIAL APPROVAL CRITERIA

1. **Cold Agglutinin Disease (CAD)**
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient weighs ≥ 39 kg; **AND**
   C. Patient has a history of at least one sign or symptom associated with cold agglutinin disease; **AND**
   Note: Examples include symptomatic anemia (e.g., anemia associated with fatigue, weakness, shortness of breath, heart palpitations, lightheadedness, chest pain), acrocyanosis, Raynaud's syndrome, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event (e.g., thrombosis).
   D. According to the prescriber, the patient has evidence of chronic hemolysis; **AND**
   E. Patient meets the following diagnostic criteria (i **and** ii):
      i. Direct antibody test strongly positive for C3d and negative or only weakly positive for immunoglobulin G; **AND**
      ii. Cold agglutinin antibody titer ≥ 64 at 4°C (approximately 40°F); **AND**
   F. At baseline (prior to the initiation of Enjaymo), patient meets both of the following (i **and** ii):
      i. Hemoglobin ≤ 10 g/dL; **AND**
      ii. Total bilirubin above the upper limit of normal, based on the reference range for the reporting laboratory; **AND**
   G. According to the prescriber, secondary causes of cold agglutinin syndrome have been excluded; **AND**
   Note: Examples of secondary causes of cold agglutinin syndrome include infection, rheumatologic diseases, and active hematologic malignancies.
   H. Enjaymo is prescribed by or in consultation with a hematologist.

RENEWAL CRITERIA:

1. Member is responding positively to therapy, as determined by the prescriber; **AND**
2. Member has not experienced unacceptable toxicity from the drug

Dosing/Administration:

Enjaymo is given intravenously; after a once weekly loading phase for two doses, maintenance dosing is given once every 2 weeks. Dosing is weight-based up to a maximum of 7,500 mg. Enjaymo is supplied as a solution in single-dose vials.

Applicable Procedure Codes

Code	Description
J1302	Injection, sutimlimab-jome, 10 mg; 1 billable unit = 10 mg

Applicable NCDs

Code	Description
80203-0347-01	Injection, for Intravenous Use (Enjaymo™)

ICD-10 Diagnoses

Code	Description
D59.12	Cold autoimmune hemolytic anemia

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/4/2025	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	3/18/2024	Annual Review: Updated dosing limits, no criteria changes
EmblemHealth & ConnectiCare	07/05/2023	Annual Review: Removed codes: C9094, J3590, C9399, added code: J1302 Removed ICD-10 codes D59, D55-59, D59.1 Updated length of authorization from 12 months to 6 months
EmblemHealth & ConnectiCare	5/12/2022	New Policy

References

1. Enjaymo™ [package insert]. Waltham, MA: Bioverativ USA Inc.; February 2022
2. Roth A, Barcellini W, D'Sa S, et al. Sutimlimab in Cold Agglutinin Disease. N Engl J Med. 2021;384(14):1323-1334
3. Roth A, Barcellini W, D'Sa S, et al. Inhibition of Complement C1s with Sutimlimab in Patients with Cold Agglutinin Disease (CAD): Results from the Phase 3 Cardinal Study. Blood. 2019. 134 (Supplement_2): LBA-2. https://doi.org/10.1182/blood2019-132490
4. Roth A, Barcellini W, D'Sa S, et al. Inhibition of Complement C1s with Sutimlimab in Patients with Cold Agglutinin Disease (CAD): Interim Results of the Phase 3 Cardinal Study Long-Term Follow-up. Blood. 2020. 136 (Supplement 1): 24–25. https://doi.org/10.1182/blood-2020-138909