

Medical Policy:

Enjaymo™ (sutimlimab-jome) Intravenous Infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.352	March 18, 2024	May 12, 2022

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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

Body-weight range	Dose (mg)	# of ENJAYMO Vials Needed	ENJAYMO volume
39 kg to <70 kg	6500	6	130 mL
70 kg to <75 kg	6500	6	130 mL
≥75 kg	7500	7	150 mL

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	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>