Enjaymo® (sutimlimab-jome)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 770 billable units weekly for two doses, then 770 billable units every 2 weeks thereafter

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria [1-2]

- Provider will confirm that member is vaccinated against encapsulated bacteria [e.g., Streptococcus pneumoniae, Haemophilus influenzae (type B), Neisseria meningitidis (serogroups A, C, W, Y and B), etc.] at least two weeks prior to initiation of therapy in accordance with the most current Advisory Committee on Immunization Practices (ACIP) recommendations and will continue to be revaccinated in accordance with ACIP recommendations *(Note: If urgent therapy is indicated in a member who is not up to date on their vaccines, administer vaccine(s) as soon as possible)*; **AND**
- Member does not have an active chronic systemic infection (e.g., hepatitis B, hepatitis C, or HIV, etc.); **AND**
- Will not be used in combination with another complement-inhibitor therapy or B-cell directed therapy *(Note: Not applicable when sutimlimab is used as bridge therapy to B-cell directed treatment)*; **AND**
- Member does not have systemic lupus erythematosus (SLE) or other autoimmune disease with positive anti-nuclear antibody; **AND**
- Member will avoid cold exposure where possible; **AND**

Cold-Agglutinin Disease (CAD) † Φ [1-3]

- Member has a confirmed diagnosis of CAD based on ALL of the following:
  - Chronic hemolysis
  - Positive polyspecific direct antiglobulin test (DAT)
  - Monospecific DAT strongly positive for C3d
  - Cold agglutinin titer ≥ 64 at 4°C
  - Immunoglobulin G (IgG) DAT ≤1+; **AND**
- Member has one of the following:
  - Recent blood transfusion within the previous 6 months (i.e., transfusion dependent); **OR**
  - No recent blood transfusion (i.e., within the previous 6 months or a history of >1 blood transfusion within the previous 12 months); **AND**
    - Member had an inadequate response, or has a contraindication or intolerance, to rituximab with/without bendamustine *(Note: Excludes members who require urgent use of sutimlimab due to acute hemolysis where transfusion is likely);* **AND**
- Other causes of secondary CAD have been ruled out such as coexisting diseases or conditions (i.e., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy, etc.) [***NOTE:*** *members with a history of or concomitant low-grade lymphoproliferative disease are not subject to exclusion*]; **AND**
- Documented baseline values for ALL of the following (necessary for renewal):
  - Hemoglobin (Hb) level ≤ 10 g/dL
  - Packed RBC transfusion requirement *(**NOTE:** Only applies to members that are transfusion dependent)*
  - Markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, lactate dehydrogenase [LDH], haptoglobin, etc.)

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections (viral and bacterial), severe infusion reactions, autoimmune disease (e.g., SLE), etc.; **AND**

- Member has experienced a disease response compared to pretreatment baseline based on at least one of the following**:**
  - Member was transfusion dependent prior to starting treatment; **AND**
    - Hemoglobin (Hb) response defined as an increase from baseline in Hb level ≥2 g/dL or a Hb level ≥12 g/dL without transfusion over a four week or longer time period; **OR**
    - Absence of packed RBC transfusion; **OR**
    - Member had an increase in Hb and/or decrease in transfusion requirement, to a lesser extent than the above, AND also had an improvement in the signs and symptoms (e.g., fatigue, jaundice, shortness of breath) and/or markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, LDH, haptoglobin, etc.); **OR**
  - Member did not have a recent history of blood transfusion prior to starting treatment; **AND**
    - Hemoglobin (Hb) response defined as an increase from baseline in Hb level ≥1.5 g/dL without transfusion over a four week or longer time period; **OR**
    - Member had an increase in Hb, to a lesser extent than the above, AND also had an improvement in the signs and symptoms (e.g., fatigue, jaundice, shortness of breath) and/or markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, LDH, haptoglobin, etc.)

V. Dosage/Administration [1]

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.*

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Enjaymo 1,100 mg/22 mL single-dose vials of solution for injection: 55292-0820-xx

VII. References

1. Enjaymo [package insert]. Bridgewater, NJ; Recordati Rare Diseases Inc.; November 2024. Accessed March 2026.

2. Röth 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. doi: https://doi.org/10.1182/blood-2019-132490.
3. Hill QA, Stamps R, Massey E, et al on behalf of the British Society of Haematology. The diagnosis and management of primary autoimmune haemolytic anaemia. Br J Haematol. 2017 Feb;176(3):395-411. doi: 10.1111/bjh.14478. Epub 2016 Dec 22. PMID: 28005293n.
4. Röth A, Berentsen S, Barcellini W, et al. Sutimlimab in patients with cold agglutinin disease: results of the randomized placebo-controlled phase 3 CADENZA trial. Blood. 2022 Sep 1;140(9):980-991. Doi: 10.1182/blood.2021014955.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D59.12	Cold autoimmune hemolytic anemia

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify

benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC