

Policy Name:	Enjaymo (sutimlimab)	Policy #:	3169P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Enjaymo (sutimlimab).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Enjaymo (sutimlimab) under the specialty medical benefit when the following criteria have been met.

Criteria

1. Cold Agglutinin Disease

- 1.1 Diagnosis of primary cold agglutinin disease (CAD) as evidenced by the following:
 - Evidence of hemolysis (eg, high reticulocyte count, high lactate dehydrogenase [LDH], low haptoglobin)
 - Positive direct antiglobulin (Coombs) test for C3
 - Cold agglutinin titer of ≥ 64 at 4°C
- 1.2 Age 18 years or older
- 1.3 Hemoglobin level ≤ 10.0 g/dL
- 1.4 Bilirubin level above normal reference range
- 1.5 Prescribed by or in consultation with a hematologist (doctor of blood disorders) or other CAD specialist
- 1.6 Presence of one or more symptoms associated with CAD: symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event
- 1.7 Documented trial of cold avoidance efforts (utilizing warm clothing when outdoors, avoiding cold rooms or environments, cold liquids, etc)
- 1.8 Documented trial and failure or contraindication to rituximab with or without bendamustine
- 1.9 Documentation of vaccination against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)

2. Exclusion Criteria

- 2.1 Secondary cold agglutinin syndrome such as autoimmune hemolytic anemia related to underlying viral infection, autoimmune disorder or lymphoid malignancy
- 2.2 Use in combination with rituximab and/or bendamustine

3. Approval Period

- 3.1 Initial approval: 6 months
- 3.2 Reauthorization: 12 months with documented benefit from therapy (as evidenced by decreased need for transfusions or resolution of symptoms)

CPT Codes

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HCPCS Codes

J1302	Injection, sutimlimab-jome, 10 mg
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References

1. Enjaymo (sutimlimab) [prescribing information]. Waltham, MA: Bioverativ USA Inc; February 2024.
2. Röth A, Barcellini W, D'Sa S, et al. Sutimlimab in cold agglutinin disease. *N Engl J Med*. 2021;384(14):1323-1334.
3. Berentsen S, Barcellini W, D'Sa S, et al. Cold agglutinin disease revisited: a multinational, observational study of 232 patients. *Blood* 2020; 136:480.
4. National Organization for Rare Disorders (NORD) Rare Disease Database. Cold Agglutinin Disease. Updated November 17, 2020. Accessed December 2022. <https://rarediseases.org/rare-diseases/cold-agglutinin-disease/>
5. Berentsen S, Ulvestad E, Gjertsen BT, et al. Rituximab for primary chronic cold agglutinin disease: a prospective study of 37 courses of therapy in 27 patients. *Blood* 2004; 103:2925.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.