PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Enjaymo (sutimlimab)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Enjaymo is a classical complement inhibitor indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD). The approval of Enjaymo was based on results from the 26-week, open-label, Phase 3 Cardinal study, which evaluated 24 patients with CAD who received Enjaymo for a period of 6 months. In the study, more than half of study participants responded to treatment with Enjaymo. Response was defined as an increase in hemoglobin of 2 g/dL or greater; no red blood cell transfusions after the first 5 weeks of treatment; and no other therapies for CAD.

Enjaymo (sutimlimab) will be considered for coverage when the following criteria are met:

Cold Agglutinin Disease

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with hematologist or CAD specialist; AND
3. Member has a diagnosis of primary Cold Agglutinin Disease confirmed by a cold agglutinin titer of ≥64;
4. Member has documentation of one or more of the following symptoms: symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event
5. Member must have documentation of at least one blood transfusion within the last 6 months; AND
6. Member has a documented hemoglobulin level ≤10.0 g/dL; AND
7. Member has a documented bilirubin level above normal reference range; AND
8. Member is NOT using in combination with rituximab; AND
9. **Dosage allowed/Quantity limit:** Initiate Enjaymo intravenously weekly for the first two weeks, with administration every two weeks thereafter:
   For patients weighing 39 kg to less than 75 kg: 6,500 mg by intravenous infusion (6 vials).
   For patients weighing 75 kg or more: 7,500 mg by intravenous infusion (7 vials).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Labs must show the member's hemoglobulin has increased by at least 2 g/dL; OR
2. Chart notes must show improvement or stabilized signs and symptoms of disease (increased quality of life, change in bilirubin, decrease in the number of blood transfusions).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Enjaymo (sutimlimab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/21/2022	New policy for Enjaymo created.

References:

1. Enjaymo [package insert]. Waltham, MA; Bioverativ USA Inc. February 2022.
2. Tvedt THA, et al. Sutimlimab, an investigational C1s inhibitor, effectively prevents exacerbation of hemolytic anemia in a patient with cold agglutinin disease undergoing major surgery. Am J Hematol. 2022 Feb 1;97(2):E51-E54.
3. Röth A, et al. Sutimlimab in Cold Agglutinin Disease. N Engl J Med. 2021 Apr 8;384(14):1323-1334.
4. Gabbard AP, Booth GS. Cold Agglutinin Disease. Clin Hematol Int. 2020;2(3):95-100.

Effective date: 01/01/2023
Revised date: 03/21/2022