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5.85.045

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	March 04, 2022
Subject:	Enjaymo	**Page:**	1 of 4

Last Review Date: March 7, 2025

Enjaymo

Description

Enjaymo (sutimlimab-jome)

Background
Enjaymo (sutimlimab-jome) is an immunoglobulin G (IgG) monoclonal antibody (mAb) that inhibits the classical complement pathway by binding to complement protein component 1,s (C1s). In cold agglutinin disease (CAD), a component of the immune system (the classical complement pathway) marks red blood cells for hemolysis. In patients with CAD, the bone marrow cannot compensate for the loss of blood cells due to hemolysis, ultimately leading to anemia and its symptoms (1).

Regulatory Status
FDA-approved indication: Enjaymo is a classical complement inhibitor indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD) (1).

Enjaymo can increase the risk for serious infection. Patients should be vaccinated against encapsulated bacteria at least two weeks prior to starting treatment. Patients should be monitored for signs and symptoms of infections (1).

Infusion-related reactions and autoimmune diseases have also occurred. Patients should be monitored for the signs and symptoms of infusion related reactions and autoimmune diseases. If either condition occurs while being treated with Enjaymo, they should be managed as medically appropriate (1).

Patients that discontinue or have an interruption in treatment with Enjaymo can experience recurrent hemolysis. Patients should be monitored for the signs and symptoms of hemolysis if treatment with Enjaymo is interrupted (1).

The safety and effectiveness of Enjaymo in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Enjaymo may be considered **medically necessary** if the conditions indicated below are met.

Enjaymo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Cold agglutinin disease (CAD)

AND ALL of the following:

1. Patient has **ONE** of the following:
    a. Patient has been or will be vaccinated against encapsulated bacteria at least 2 weeks prior to starting treatment (e.g., Pneumococcal, Meningococcal, and Hib vaccinations)
    b. Patient is not vaccinated against encapsulated bacteria but has an urgent need of Enjaymo treatment **AND** prescriber agrees to vaccinate the patient against encapsulated bacteria as soon as possible

2. Prescriber agrees to monitor patient for signs and symptoms of serious infections

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Cold agglutinin disease (CAD)

AND ONE of the following:

1. Hemoglobin level ≥12 g/dL **OR** increase in hemoglobin by ≥2 g/dL from baseline
2. Patient has had a reduction in need for RBC transfusion

AND the following:

1. Prescriber agrees to monitor patient for signs and symptoms of serious infections

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Enjaymo is a classical complement inhibitor indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD). Enjaymo has warnings for increased risk of serious infections, autoimmune disease, infusion-related reactions, and recurrent hemolysis after treatment discontinuation. The safety and effectiveness of Enjaymo in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Enjaymo while maintaining optimal therapeutic outcomes.

References

1. Enjaymo [package insert]. Waltham, MA: Bioverativ USA Inc.; February 2024.

Policy History

Date	Action
March 2022	Addition to PA
June 2022	Annual review
March 2023	Annual editorial review and reference update. Per PI update, removed initiation requirement that patient requires RBC transfusions to manage condition. Changed policy number to 5.85.045
June 2023	Annual review and reference update
December 2023	Annual review
March 2024	Annual review
June 2024	Annual review and reference update
September 2024	Annual review
December 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.