

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Enjaymo Clinical Edit
<b>First Implementation Date:</b>	October 20, 2022
<b>Revised Date:</b>	N/A
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Enjaymo™ (sutimlimab-jome).

**Why Issue Selected:** Enjaymo™ was FDA-approved on February 4, 2022, to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD). Cold agglutinins are predominantly IgM autoantibodies that are directed against RBC antigens and have an optimum temperature of 37 to 39 degrees Fahrenheit. When exposed to temperatures below the normal core body temperature, they bind to antigens on the surface of RBCs and eventually lead to the destruction of the RBC resulting in hemolytic anemia. CAD is a form of autoimmune hemolytic anemia (AIHA) with a prevalence of approximately 16 people per million. CAD normally affects patients aged 40 to 80 years, with a median age at symptom onset of 65 years.

Enjaymo is an immunoglobulin G (IgG) monoclonal antibody that inhibits the classical complement pathway. This inhibition leads to reduced hemolysis in patients with CAD. Enjaymo is administered as an intravenous (IV) infusion every two weeks.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of

Program-Specific Information:	Drug	Cost per vial (MAC)	Cost per month (MAC)	Cost per year (MAC)
	ENJAYMO 1,100 MG/22 ML VIAL	\$1,792.78	\$25,099.20	\$326,285.96

\*cost based on 75kg participant

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Enjaymo™ (sutimlimab-jome)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

## Approval Criteria

### Initial Therapy

- Prescribed by or in consultation with an appropriate specialist in the treated disease state **AND**
- Participant is aged at least 18 years **AND**
- Documented diagnosis of primary cold agglutinin disease (CAD) confirmed by:
  - Evidence of hemolysis **AND**
  - Positive direct antiglobulin (Coombs) test for C3d only **AND**
  - Cold agglutinin titer of  $\geq 64$  at 4 degrees Celsius **AND**
  - Lack of overt malignant disease **AND**
- Documented history of at least one blood transfusion in the past 6 months **AND**
- Hemoglobin level  $\leq 10.0$  g/dL **AND**
- Bilirubin level above normal reference range, including patients with Gilbert's syndrome **AND**
- Presence of one or more symptoms associated with CAD:
  - Symptomatic anemia
  - Acrocyanosis
  - Raynaud's phenomenon
  - Hemoglobinuria
  - Disabling circulatory symptoms
  - Major adverse vascular event **AND**
- Participant not eligible for rituximab-based therapy due to one of the following:
  - Unresponsive to previous rituximab-based therapy after a minimum of six months **OR**
  - Documented medical reason why rituximab-based therapy is not appropriate or is contraindicated
- Initial approval for 6 months

### Continuation of Therapy

- Documentation of benefit from therapy including one of the following:
  - Increase in Hgb from baseline by  $\geq 2$  g/dL or achieving Hgb level of  $\geq 12$  g/dL
  - Normalization of LDH and/or bilirubin levels
  - Decrease in transfusion burden
- Continued approval for 12 months

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant

## Required Documentation

Laboratory Results:  
MedWatch Form:


Progress Notes:  
Other:

X

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

6 months

*SmartPA Clinical Proposal Form*

© 2022 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

## References

- Enjaymo™ (sutimlimab-jome) [package insert]. Waltham, MA: Bioverativ USA Inc.; February 2022.
- IPD Analytics: New Drug Review: Enjaymo (sutimlimab-jome). Accessed March 30, 2022.
- Berentsen S. Cold agglutinin disease. Hematology Am Soc Hematol Educ Program 2016; 2016(1):226–231. <https://doi.org/10.1182/asheducation-2016.1.226>. Accessed March 30, 2022
- Roth A, Barcellini W, D'sa S, et al. Sutimlimab in cold agglutinin disease. N Engl J Med 2021;384:1323-1334. [Sutimlimab in Cold Agglutinin Disease | NEJM](#). Accessed March 30, 2022.
- Swiecicki P, Hegerova L, Gertz M; Cold agglutinin disease. Blood 2013;122(7):1114–1121. <https://doi.org/10.1182/blood-2013-02-474437>. Accessed March 30, 2022.
- Berentsen S. How I treat cold agglutinin disease. Blood 2021;137(10):1295–1303. <https://doi.org/10.1182/blood.2019003809>. Accessed March 30, 2022.
- Brugnara C, Berentsen S. Cold agglutinin disease. UpToDate. [Cold agglutinin disease - UpToDate](#). Accessed March 31, 2022.
- Berentsen S, Barcellini W, D'Sa S, et al. Cold agglutinin disease revisited: a multinational, observational study of 232 patients. Blood 2020;136(4):480–488. <https://doi.org/10.1182/blood.2020005674>. Accessed March 30, 2022.