



SmartPA Criteria Proposal

Drug/Drug Class:	Enjaymo Clinical Edit		
First Implementation Date:	TBD		
Proposed Date:	June 16, 2022		
Prepared for:	MO HealthNet		
Prepared by:	MO HealthNet/Conduent		
Criteria Status:	 □Existing Criteria □Revision of Existing Criteria ⊠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 ☑ Clinical Edit 			
	Appropriate Indications				
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

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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:
 - o Evidence of hemolysis AND
 - o Positive direct antiglobulin (Coombs) test for C3d only AND
 - Cold agglutinin titer of \geq 64 at 4 degrees Celsius **AND**
 - o Lack of overt malignant disease AND
- Documented history of at least one blood transfusion in the past 6 months AND
- Hemoglobin level ≤ 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:
 - o Symptomatic anemia
 - o Acrocyanosis
 - Raynaud's phenomenon
 - o Hemoglobinuria
 - Disabling circulatory symptoms
 - Major adverse vascular event AND
- Participant not eligible for rituximab-based therapy due to one of the following:
 - o 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 ≥ 2 g/dL or achieving Hgb level of ≥ 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:



Disposition of Edit

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

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Default Approval Period

6 months

References

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