SmartPA Criteria Proposal

Drug/Drug Class:	Enjaymo Clinical Edit
First Implementation Date:	October 20, 2022
Proposed Date:	July 18, 2023
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.

On January 25, 2023, Enjaymo was FDA approved for an expanded indication which includes adults without a transfusion history with CAD.

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 Enjaymo.

Program-Specific Information:

Drug	Cost per vial (MAC)	Cost per month (MAC)	Cost per year (MAC)
ENJAYMO 1,100 MG/22 ML VIAL	$1,879.90	$25,635.00	$320,437.50

*cost based on 75kg participant

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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 ≥ 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 ≤ 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 ≥ 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:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	X

Disposition of Edit

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

Default Approval Period

6 months

References

- Enjaymo™ (sutimlimab-jome) [package insert]. Waltham, MA: Bioverativ USA Inc.; January 2023.
- IPD Analytics: New Drug Review: Enjaymo (sutimlimab-jome). Accessed March 30, 2022.
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- 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.
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