

Drug Policy:

Enjaymo™ (sutimlimab-jome)

POLICY NUMBER UM ONC_1458	SUBJECT Enjaymo™ (sutimlimab-jome)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 03/09/22, 04/13/22, 05/11/22, 03/08/23, 03/13/24	APPROVAL DATE March 13, 2024	EFFECTIVE DATE March 29, 2024	COMMITTEE APPROVAL DATES 03/09/22, 04/13/22, 05/11/22, 03/08/23, 03/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Enjaymo (sutimlimab-jome) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

B. Cold Agglutinin Disease (CAD)

1. Enjaymo (sutimlimab-jome) may be used as monotherapy in members with a confirmed diagnosis of primary Cold Agglutinin Disease (CAD), a Hgb less than or equal to 10 g/dL within the last 4 weeks, and recent history of blood transfusion within 6 months.

III. EXCLUSION CRITERIA

- A. The member continued to require blood transfusions or did not achieve a rise in Hgb greater than or equal to 2 g/dL after 5 weeks of Enjaymo (sutimlimab-jome) treatment.
- B. Presence of any overt malignancy (excludes Cold Agglutinin Disease which is itself a low-grade monoclonal B-cell lymphoproliferative disorder detectable in the blood or bone marrow but without any radiologic evidence of neoplasm).
- C. Cold agglutinin disease secondary to infection, rheumatologic disease, or other autoimmune disorders (e.g., systemic lupus erythematosus).
- D. Dosing exceeds single dose limit of Enjaymo (sutimlimab-jome) 6.5 gm (for weight less than 75 kg) or 7.5 gm (for weight greater than or equal to 75 kg).
- E. Treatment with Enjaymo (sutimlimab-jome) exceeds the maximum months duration limit of 24 months .
- F. Investigational use of Enjaymo (sutimlimab-jome) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
 - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
 - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
 - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 - 4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
 - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
 - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
 - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

- A. Röth A, et al. CARDINAL Trial. Sutimlimab in Cold Agglutinin Disease. N Engl J Med. 2021 Apr 8;384(14):1323-1334.
- B. Enjaymo prescribing information. Bioverativ USA Inc. Waltham, MA 2022.
- C. Clinical Pharmacology Elsevier Gold Standard 2022.
- D. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.
- E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.
- F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.
- G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.
- H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.