Medical Policy

Enjaymo™ (sutimlimab-jome)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-123
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan*: ALL *Small Group:* ALL *Medicare Advantage*: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Enjaymo™ (sutimlimab-jome) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Enjaymo will be provided for six (6) months and may be renewed.

- Max Units (per dose and over time): 750 billable units (7500 mg) weekly for two doses then every 2 weeks thereafter

Medical Policy

Initial

A. Patient is at least 18 years of age; **AND**
B. Patient must be vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Haemophilus influenzae, Neisseria meningitidis, etc.) at least two weeks prior to initiation of therapy in accordance with the most current Advisory Committee on Immunization Practices (ACIP) recommendations and will continue to be revaccinated (Note: If urgent therapy is indicated in an unvaccinated patient, administer vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis); **AND**
C. Patient does not have an active chronic systemic infection (i.e., hepatitis B, hepatitis C, or HIV, etc.); **AND**
D. Enjaymo will not be used in combination with another complement-inhibitor therapy (i.e., ravulizumab, eculizumab, pegcetacoplan, avacopan, etc.) or B-cell directed therapy (i.e., rituximab); **AND**
E. Patient does NOT have systemic lupus erythematosus (SLE) or other autoimmune disease with positive anti-nuclear antibody; **AND**
F. Patient will avoid cold exposure where possible; **AND**

Cold-Agglutinin Disease (CAD)

A. Patient has a confirmed diagnosis of CAD based on the following:
    a. chronic hemolysis
    b. polyspecific direct antiglobulin test (DAT)
    c. monospecific DAT specific for C3d
    d. cold agglutinin titer ≥64 at 4°C
    e. IgG DAT ≤1+
    f. recent blood transfusion in the 6 months prior; **AND**
B. Patient is transfusion dependent on packed red blood cells (PRBCs) due to chronic hemolysis; **AND**
C. Other causes of CAD have been ruled out such as coexisting diseases or conditions (i.e., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy, etc.) [Note; patients with a history of or concomitant low-grade lymphoproliferative disease are not subject to exclusion]; **AND**
D. Documented baseline values for both of the following (necessary for renewal): hemoglobin level, packed RBC transfusion requirement, markers of hemolysis

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, severe infusion reactions, autoimmune disease (e.g., SLE), etc.; **AND**
C. Patient has experienced a disease response compared to pretreatment baseline:
    a. Hemoglobin response defined as an increase from baseline in Hgb level ≥2 g/dL or a
    b. Hgb level ≥12 g/dL without transfusion over a four week or longer time period; OR
    c. Absence of packed RBC transfusion; OR
    d. Patient had an increase in Hb and/or decrease in transfusion requirement, to a lesser extent than the above, AND also had an improvement in the signs and

symptoms (e.g., fatigue, jaundice, shortness of breath) and/or markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, LDH, haptoglobin, etc.)

LIMITATIONS/EXCLUSIONS

1) Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. ENJAYMO™ (sutimlimab-jome) injection, for intravenous use. Initial U.S. Approval: 2022
   a. ENJAYMO (sutimlimab-jome) injection is a clear to slightly opalescent, colorless to slightly yellow, preservative-free solution supplied as one 1,100 mg/22 mL (50 mg/mL) single-dose vial per carton

CODING

Applicable NDC Codes	
80203-0347-xx	Enjaymo 1,100 mg/22 mL single-use vials of solution for injection

Applicable Procedure Code	
J1302	Injection, sutimlimab-jome, 10 mg

Applicable ICD-10 Codes	
D59.12	Cold autoimmune hemolytic anemia

EVIDENCE BASED REFERENCES

1. Enjaymo [package insert]. Waltham, MA; Bioverativ USA, Inc; February 2022. Accessed July 2022.

Policy History

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan Care's policies on clinical criteria and policy development.

Approval Body	Pharmacy and Therapeutics Committee
Original Effective Date	July 26, 2022
Version Date	V1 – July 26, 2022 V2 – March 01, 2023 – Adopted by MA UMC, new HCPCS code V3 – January 01, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan