Enjaymo™ (sutimlimab-jome)

Humana

Pharmacy Coverage Policy

Effective Date: July 27, 2022
Revision Date: July 27, 2022
Review Date: July 20, 2022
Line of Business: Medicare, Commercial, Medicaid - Ohio
Policy Type: Prior Authorization

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

Enjamyo (sutimlimab-jome) is a humanized monoclonal antibody (IgG_4)

Enjaymo (sutimlimab-jome) is an immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody (mAb) that inhibits the classical complement pathway and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4. Sutimlimab-jome does not inhibit the lectin and alternative pathways. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of red blood cells, resulting in inhibition of hemolysis in patients with cold agglutinin disease.

Enjaymo (sutimlimab-jome) is indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).

Sutimlimab-jome is available as Enjaymo 1,100 mg/22mL (50mg/1mL) preservative free solution for intravenous use.

Coverage

Please note the following regarding medically accepted indications:

Determination

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Enjaymo (sutimlimab-jome) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Cold Agglutinin Disease

Member must meet ALL of the following criteria:

- Diagnosis of primary cold agglutinin disease (CAD) as defined by the following:
  - Chronic hemolysis (e.g. high reticulocyte count, high LDH, high indirect bilirubin, low haptoglobin) **AND**
  - Direct antiglobulin test positive for polyspecific antibodies and strongly positive for C3d; **AND**
  - Cold agglutinin titer greater than or equal 64 at 4 degrees Celsius

- Hemoglobin level less than or equal to 10 g/dL
- Total bilirubin level above normal reference range
- Vaccinated against encapsulated bacteria at least 2 weeks prior to initiation of Enjaymo therapy according to ACIP recommendations
- Not received rituximab within 3 months of initiation or rituximab plus chemotherapy within 6 months of initiation and will not receive concomitant rituximab or rituximab plus chemotherapy with Enjaymo
- Does not carry a diagnosis of systemic lupus erythematosus

Continuation of Therapy
Member must meet ALL of the following criteria:

- Efficacy of Enjaymo (sutimlimab-jome) as defined by one of the following:
  - Increase in hemoglobin of 2g/dL or more while on therapy; **OR**
  - Normalization of hemoglobin to 12g/dL or more while on therapy; **OR**
  - Decreased need for red blood cell transfusions while on therapy;
- Not receiving concomitant therapy with rituximab and/or chemotherapy

Enjaymo (sutimlimab-jome) will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Enjaymo (sutimlimab-jome) therapy is not considered medically necessary for members with the following concomitant conditions:

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Enjaymo (sutimlimab-jome).

Cold Agglutinin Disease
Cold agglutinin disease (CAD) is a form of autoimmune hemolytic anemia (AIHA) in which cold agglutinins (IgM antibodies against red blood cell antigens) can cause clinical symptoms related to RBC agglutination in cooler parts of the body and hemolytic anemia in the setting of viral infection, autoimmune disorder, or lymphoid malignancy.
Cold agglutinin disease is distinguished from cold agglutinin syndrome in that cold agglutinin disease is a clonal, low-grade B-cell lymphoproliferative disorder that can be detected in blood or marrow in patients with no clinical or radiologic evidence of malignant conditions.
Symptoms of CAD may be caused by agglutination or hemolysis leading to fatigue, shortness of breath, palpitations, hematuria, weakness, jaundice, bluish or reddish discoloration of the skin, and cold induced circulatory symptoms.

Warnings and Precautions

- Serious Infections
  - May increase susceptibility to serious infections, including infections caused by encapsulated bacteria such as Neisseria meningitides (any serogroup), Streptococcus pneumoniae, and Haemophilus influenzae.
  - Vaccinate patients for encapsulated bacteria according to the most current ACIP recommendations for patients with persistent complement deficiencies. Revaccinate patients in accordance with ACIP recommendations
  - ACIP recommendations for meningiococcal vaccines can be accessed via the following: http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html

- Infusion-Related Reactions
  - Monitor patients for infusion-related reactions and interrupt if a reaction occurs. Discontinue Enjaymo infusion and institute appropriate supportive measures if signs of hypersensitivity reactions, such as cardiovascular instability or respiratory compromise, occur.

- Risk of Autoimmune Disease
  - Based on its mechanism of action, Enjaymo may potentially increase the risk for developing autoimmune diseases such as systemic lupus erythematosus (SLE). Development of systemic lupus erythematosus (SLE) has been associated with inherited classical complement deficiency. Patients with SLE or autoimmune disease with positive anti-nuclear antibody were excluded from clinical trials with Enjaymo. Monitor patients being treated with Enjaymo for signs and symptoms and manage medically.

- Recurrent Hemolysis after Enjaymo Discontinuation
  - If treatment with Enjaymo is interrupted, closely monitor patients for signs and symptoms of recurrent hemolysis, e.g., elevated levels of total bilirubin or lactate dehydrogenase (LDH) accompanied by a decrease in hemoglobin, or reappearance of symptoms such as fatigue, dyspnea, palpitations, or hemoglobinuria. Consider restarting Enjaymo if signs and symptoms of hemolysis occur after discontinuation.

- For complete product information, refer to the product label

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Enjaymo; sutimlimab-jome; cold agglutinin disease; CAD; intravenous

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. URL: http://www.clinicalpharmacology.com.Updated periodically.
2. Lexi-Comp [database online]. Hudson, OH Lexi-comp, Inc.: URL http://online.lexi.com Updated periodically.
3. Micromedex Healthcare Series: DRUGDEX. Thomson Micromedex, Greenwood Village, CO. Updated periodically.
4. Enjaymo [package insert]. Bridgewater, NJ: Sanofi; Revised February 2022.