FirstChoice VIP CARE
by Select Health of South Carolina

Medical Policy Bulletin
Title:
Sutimlimab-jome (Enjaymo)
Policy #:
MA08.145a

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

SUTIMLIMAB-JOME (ENJAYMO)
Sutimlimab-jome (Enjaymo) is considered medically necessary and, therefore, covered for the treatment of adult individuals to decrease the need for red blood cell (RBC) transfusion due to hemolysis with cold agglutinin disease (CAD) when all of the following criteria are met:

- The individual confirmed diagnosis of primary cold agglutinin disease (CAD) based on all of the following criteria:
  - Chronic hemolysis
  - Polyspecific direct antiglobulin test (DAT) positive
  - Monospecific DAT is strongly positive for C3d
  - Cold agglutinin titer >= 64 at 4 degrees Celsius
  - Immunoglobulin G (IgG) DAT less than or equal to (<=) 1+
  - No overt malignant disease (e. i., an aggressive or malignant disease that is easily observable; clinically obvious; symptomatic, and often rapid organ damage)
- History of at least one documented blood transfusion within six months of treatment
- Hemoglobin level <= 10.0 gram per deciliter (g/dL)
- Bilirubin level above the normal reference range, including individuals with Gilbert's Syndrome
- The individual has a bodyweight of greater than or equal to (>=) 39 kilogram (kg) at the initiation of the treatment
- The individual does **not** have any of the following conditions:

  - Cold agglutinin syndrome secondary to an infection, rheumatologic disease, or active hematologic malignancy
  - Clinically relevant infection of any kind within the month preceding treatment (eg, active hepatitis C, pneumonia)
  - Clinical diagnosis of systemic lupus erythematosus (SLE) or other autoimmune disorders with anti-nuclear antibodies at the initiation of the treatment.
- The individual has all of the following:
  - Negative hepatitis panel (including hepatitis B surface antigen and/or hepatitis C virus antibody) prior to or at the initiation of the treatment
  - Negative human immunodeficiency virus (HIV) antibody at the initiation of the treatment
  - Vaccination against encapsulated bacteria at least two weeks prior to the treatment

EXPERIMENTAL/INVESTIGATIONAL

All other uses for sutimlimab-jome (Enjaymo), are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

An Individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

Guidelines

DRUG INFORMATION

In accordance with US Food and Drug Administration (FDA) prescribing information, dosing and frequency for sutimlimab-jome (Enjaymo) is weight-based dosage weekly for two weeks then every two weeks:

- For individuals weighing 39 kg to less than 75 kg: 6,500 mg by intravenous infusion
- For individuals weighing 75 kg or more: 7,500 mg by intravenous infusion

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, sutimlimab-jome (Enjaymo) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Sutimlimab-jome (Enjaymo) was approved by the FDA on February 4, 2022 for the treatment of adult individuals to decrease the need for red blood cell (RBC) transfusion due to hemolysis with cold agglutinin disease (CAD).

PEDIATRIC USE

The safety and effectiveness of sutimlimab-jome (Enjaymo) have not been established in the pediatric population.

Description

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

PEER-REVIEWED LITERATURE

SUMMARY
The safety of Enjaymo in patients with a confirmed diagnosis of CAD and history of blood transfusion in the 6 months prior to study enrollment was evaluated in a six-month, open-label single-arm trial (CARDINAL) (n=24). The median duration of treatment was 26.1 weeks and 92% completed 26 weeks of therapy. In CARDINAL, the most common adverse reactions occurring in ≥10% of patients were respiratory tract infection, viral infection, diarrhea, dyspepsia, cough, arthralgia, arthritis, and peripheral edema. Serious adverse reactions were reported in 13% (3/24) of patients who received Enjaymo. These serious adverse reactions were streptococcal sepsis and staphylococcal wound infection (n=1), arthralgia (n=1), and respiratory tract infection (n=1). None of the adverse reactions led to discontinuation of ENJAYMO in CARDINAL. Dosage interruptions due to an adverse reaction occurred in 17% (4/24) of patients who received ENJAYMO. Adverse reactions occurring in ≥5% or more patients in CARDINAL

OFF-LABEL INDICATIONS

There may be additional indications contained in the policy section of this document due to evaluation of criteria highlighted in the company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

References

ClinicalTrials.gov. A Study to Assess the Efficacy and Safety of BIVV009 (Sutimlimab) in Participants With Primary Cold Agglutinin Disease Who Have a Recent History of Blood Transfusion (Cardinal Study). ClinicalTrials.gov Identifier: NCT03347396. First Posted: November 20, 2017. Last Update Posted: October 1, 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT03347396. Accessed March 20, 2022.

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Lexi-Drugs Compendium. Sutimlimab-jome. [Lexicomp Online Web site]. 02/07/2022. Available at: http://online.lexi.com/lco/action/home [via subscription only]. Accessed March 20, 2022.

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Truven Health Analytics. Micromedex® DrugDex® Compendium. Sutimlimab-jome (Enjaymo). Greenwood Village, CO. [Micromedex® Solutions Web site]. 03/15/2022. Available at: http://www.micromedexsolutions.com/micromedex2/librarian [via subscription only]. Accessed March 20, 2022.

US Food and Drug Administration (FDA). Center for Drug Evaluation and Research. Drugs@FDA. Sutimlimab-jome (Enjaymo). [FDA Web site]. Original: 02/04/22. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed March 20, 2022.

US Food and Drug Administration (FDA). Sutimlimab-jome (Enjaymo) prescribing information & approval letter. [FDA Web site]. 02/2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/761164Orig1s000ltr.pdf. Accessed March 20, 2022.

Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
D59.12 Cold autoimmune hemolytic anemia

HCPCS Level II Code Number(s)
J1302 Injection, sutimlimab-jome, 10 mg

Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.145a:

05/07/2024	The policy has been reviewed and reissued to communicate the Company's continuing position on sutimlimab-jome (Enjaymo).
09/05/2023	The policy has been reviewed and reissued to communicate the Company's continuing position on sutimlimab-jome (Enjaymo).
10/01/2019	This policy has been identified for the HCPCS code update, effective 10/01/2019. The following HCPCS code has been **added** to this policy: J1302 Inj, sutimlimab-jome, 10 mg The following HCPCS codes have been **removed** from this policy: C9094 Inj, sutimlimab-jome, 10 mg J3590 Unclassified biologics

Revisions From MA08.145:

07/01/2022	This version of the policy will become effective 07/01/2022. This new policy has been developed to communicate the Company's coverage position and criteria for sutimlimab-jome (Enjaymo).

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Version Effective Date:
10/01/2022
Version Issued Date:
09/30/2022
Version Reissued Date:
05/07/2024