RX.PA.075.CCH ENJAYMO (SUTIMLIMAB-JOME)

The purpose of this policy is to define the prior authorization process for Enjaymo (sutimlimab-jome) for Cold Agglutin Disease (CAD).

DEFINITIONS

CAD = Cold Agglutin Disease
Hgb = Hemoglobin

POLICY
It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Enjaymo (sutimlimab-jome), is subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:
Must meet all the criteria listed below:

- Must be age 18 years or older
- Must be prescribed by, or in consultation with, a hematologist
- Must have a diagnosis of primary cold agglutinin disease (CAD)
- Must have documentation that secondary CAD has been ruled out (i.e., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy)
- Must have the following lab values:
    - Hemoglobin (Hgb) level ≤ 10.0 g/dL
    - Bilirubin level above normal reference range
- Must have a history of at least ONE documented blood transfusion prior to therapy with Enjaymo
- Documentation (or attestation from provider) that the member has been vaccinated for encapsulated bacteria (e.g., pneumococcal, meningococcal

vaccinations) according to the most current ACIP recommendations for patients with persistent complement deficiencies
- Enjaymo must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon the following:

- Documentation the member is responding to therapy as evidenced by ONE of the following:
  - Decrease in number of transfusions/blood units required **OR**
  - Increase in hemoglobin by >2 g/dL **OR**
  - Hemoglobin level ≥ 12g/dL
- Must not be taking rituximab with Enjaymo
- Enjaymo must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J1302	Enjaymo	Injection, sutimlimab-jome, 10mg

References:

1. Enjaymo [Prescribing Information]. Waltham, MA: Bioverativ USA, Inc.; February 2022.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED

Initial review	XX/XX

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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