Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 264.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Enjaymo (sutimlimab-jome)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Enjaymo (sutimlimab-jome)

II. Purpose/Objective:
To provide a policy of coverage regarding Enjaymo (sutimlimab-jome).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Enjaymo (sutimlimab-jome) is a humanized immunoglobulin G (IgG4) monoclonal antibody which targets and inhibits the classical complement pathway by specifically binding to the complement protein component 1, s subcomponent (C1s), which is a serine protease that cleaves C4. Inhibition of the classical complement pathway at the C1s level prevents deposition of complement opsonins on red blood cell (RBC) surfaces, resulting in inhibition of hemolysis in cold agglutinin disease. Sutimlimab does not inhibit the lectin and alternative pathways.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Enjaymo (sutimlimab-jome) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Enjaymo is prescribed by or in consultation with hematologist **AND**
- Medical record documentation of a diagnosis of primary cold agglutinin disease (CAD) confirmed by all of the following:
    - Evidence of chronic hemolysis (examples: high reticulocyte count, High LDL, high indirect bilirubin, low haptoglobin) **AND**
    - Positive polyspecific direct antiglobulin test (DAT) **AND**
    - Positive monospecific DAT specific for C3d **AND**
    - Cold agglutinin titer ≥ 64 at 4 degrees Celsius

  AND
- Medical record documentation of hemoglobin level ≤ 10.0 g/dL OR transfusion dependent for new starts **AND**
- Medical record documentation that secondary causes of cold agglutinin disease (CAD) have been ruled out **AND**
- Medical record documentation of a prescribed dose that is consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Enjaymo will not be used in combination with rituximab ± bendamustine or fludarabine **AND**
- Medical record documentation that patient is vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae subgroup B) at least 2 weeks prior to treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab ± bendamustine or fludarabine

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of Enjaymo therapy is required. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on Enjaymo therapy.

Notes:
- For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.
- Abrupt discontinuation of Enjaymo therapy may result in a recurrence of hemolysis unless the underlying condition causing cold agglutinin production has been treated.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Enjaymo [prescribing information]. Waltham, MA: Bioverativ Therapeutics Inc; February 2024.
2. Cold Agglutinin Disease. National Organization for Rare Diseases. 2023 July 17 [cited 2023 Dec 26]. Available from: https://rarediseases.org/rare-diseases/cold-agglutinin-disease/#therapies

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/19/22

Revised: 7/18/23 (Medicaid PARP statement, LOB carve out, del transfusion requirement), 12/28/23 (references added), 7/9/25 (LOB table, taglines)

Reviewed: 7/10/24

MA UM Committee approval: 12/31/23, 12/31/24, 9/10/25

DHS PARP approval: 8/12/25