OPTIMA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Enjaymo™ (sutimlimab-jome) (J3590) (Medical)

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) [NDC Unit]:

- Enjaymo 1,100 mg/22 mL (50 mg/mL) in a single-dose vial; NDC: 80203-0347-xx
- 7 vials Days 1, 8 then 7 vials every 14 days thereafter

B. Max Units (per dose and over time) [HCPCS Unit]:

- 7500 mg weekly for two doses then every 2 weeks thereafter

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied. (Trials will be verified using pharmacy claims and/or submitted chart notes.)

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Member has a diagnosis of Cold Agglutinin Disease (CAD) confirmed by **ALL** of the following:
  - ❑ Chronic hemolysis
  - ❑ Polyspecific direct antiglobulin test (DAT)
  - ❑ Monospecific DAT specific for C3d
  - ❑ Cold agglutinin titer ≥ 64 at 4°C − IgG DAT ≤1+
  - ❑ Recent blood transfusion (i.e. in the past 6 months)
- ❑ Member is transfusion dependent on packed red blood cells (PRBCs) due to chronic hemolysis

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- ❑ Other causes of CAD have been ruled out, such as coexisting diseases or conditions (e.g., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy**) [Note: members with a history of or concomitant low-grade lymphoproliferative disease are not subject to exclusion]**
- ❑ Provider has submitted baseline values for **ALL** of the following:
  - ❑ Hemoglobin level
  - ❑ Packed RBC transfusion requirement
  - ❑ Markers of hemolysis
- ❑ Member has been vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Haemophilus influenzae, Neisseria meningitidis) 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 member, administer vaccine(s) as soon as possible and provide members with two weeks of antibacterial drug prophylaxis)**
- ❑ Member does **NOT** have an active chronic systemic infection (e.g., hepatitis B, hepatitis C, or HIV)
- ❑ Medication will **NOT** be used in combination with another complement-inhibitor therapy (e.g., ravulizumab, eculizumab, pegcetacoplan, avacopan) or B-cell directed therapy (e.g., rituximab)
- ❑ Member does **NOT** have systemic lupus erythematosus (SLE) or other autoimmune disease with positive anti-nuclear antibody
- ❑ Member will avoid cold exposure where possible

Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., serious infections, severe infusion reactions, autoimmune disease (e.g., SLE))
- ❑ Member has experienced positive disease response compared to pre-treatment baseline as demonstrated by at least **ONE** of the following:
  - ❑ Hemoglobin response defined as an increase from baseline in Hgb level ≥ 2 g/dL or a Hgb level ≥ 12 g/dL without transfusion over a four week or longer time period
  - ❑ Absence of packed RBC transfusion
  - ❑ Member 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)

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(Please ensure signature page is attached to form.)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____
  NPI or DEA # of administering location: _____
  OR
- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR /NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 5/19/2022
REVISED/UPDATED: ~~5/9/2022; 6/3/2022~~ **6/24/2022**