OPTIMA HEALTH PLAN

PHARMACY/MEDICAL PRIOR AUTHORIZATION 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: Gamifant® (empalumab-lzsg) (IV Infusion) (J3590) (Medical)

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (current): _____ **Weight (within last 30 days)**: _____

Maximum Approved Dose: 10mg/kg dose given twice weekly. Medication may be approved for a maximum of 3 months or until initiation phase of stem cell transplantation

- ❑ 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.

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.

- ❑ Medication must be prescribed by a hematologist, oncologist or specialist in hemophagocytic lymphohistiocytosis
- ❑ Member must have diagnosis of primary (familial) hemophagocytic lymphohistocytosis (HLH) as confirmed by an FDA-approved genetic test (submit test results confirming diagnosis)
- ❑ Member meets five of the following criteria (must submit lab results and chart notes for documentation):
  - ❑ Persistent fever higher than 101.3° F
  - ❑ Splenomegaly
  - ❑ Cytopenia defined by at least 2 of the following (please note):
    - ❑ hemoglobin < 9 g/dL (or < 10 g/dL in infants)
    - ❑ platelets < 100 x 10^9/L
    - ❑ neutrophils < 1 x 10^9/L
  - ❑ Hypertriglyceridemia (fasting triglycerides ≥ 265 mg/dL) and/or hypofibrinogenemia (fibrinogen ≤ 1.5 g/L)

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- ❑ Hemophagocytosis in the bone marrow, spleen, or lymph nodes with no evidence of malignancy
- ❑ Ferritin ≥ 500 mcg/L
- ❑ High plasma concentration of soluble CD25 with level ≥ 2400 U/mL

❑ Prescriber has attached chart notes documenting member's intolerance to conventional therapy with etoposide, methotrexate, anti-thymocyte globulin, or cyclosporine (submit chart notes)

❑ Member has NOT previously received a stem cell transplant

❑ Member is a candidate for stem cell transplant, and emapalumab is being used as part of induction therapy or maintenance phase of stem cell transplant, which will be discontinued at initiation phase of stem cell transplant. Stem cell transplant date:_____

❑ Medication will NOT be used for treatment of secondary or acquired HLH

Authorization renewal for additional 3 months:

❑ All of the initial authorization criteria continues to be met

❑ Member does not have evidence of unacceptable toxicity and has documentation of improvement in at least 3 clinical markers (i.e. platelet count, neutrophil count, ferritin, fibrinogen; etc.)

❑ Member continues to require treatment with emapalumab as part of induction/maintenance phase of stem cell transplant; emapalumab will be discontinued at initiation phase of stem cell transplant. Stem cell transplant date: _____

Medication being provided by (check applicable box below):

❑ **Location/site of drug administration:** _____

NPI or DEA # of administering location: _____

OR

❑ **Specialty Pharmacy - PropriumRx**

(Continued on next page; signature page is required to process request.)

(Please ensure signature page is attached to form.)

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:** 2/20/2020
REVISED/UPDATED: ;