

# SENTARA COMMUNITY PLAN (MEDICAID)

## 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 1-844-305-2331. 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.

**Drug Requested:** Gamifant<sup>®</sup> (empalumab-lzsg) (IV Infusion) (J3590) (Medical)

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

DEA OR NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight: \_\_\_\_\_ Date: \_\_\_\_\_

- 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.

**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

**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 lymphohistiocytosis (HLH) as confirmed by an FDA-approved genetic test (submit test results confirming diagnosis)

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- 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<sup>9</sup>/L
    - neutrophils < 1 x 10<sup>9</sup>/L
  - Hypertriglyceridemia (fasting triglycerides ≥ 265 mg/dL) and/or hypofibrinogenemia (fibrinogen ≤ 1.5 g/L)
  - 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**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.\****