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® (empalumab-lzsg) – **Primary HLH (J9210) MEDICAL**

The Sentara Health Plans Oncology Program is administered by OncoHealth

- **For any oncology indications**, the most efficient way to submit a prior authorization request is through the **OncoHealth OneUM Provider Portal** at https://oneum.oncohealth.us. Fax to **1-800-264-6128.** OncoHealth can also be contacted by Phone: 1-888-916-2616.
- Commercial customers **NOT** enrolled in the OncoHealth program, please fax requests to Sentara Health plans at fax number 1-800-750-9692.

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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

☐ 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.

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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.

Diagnosis: Primary Hemophagocytic Lymphohistiocytosis (HLH)

Initial Authorization: 6 months

- ❑ Medication is prescribed by or in consultation with a hematologist, oncologist, immunologist, transplant specialist, or physician who specializes in hemophagocytic lymphohistiocytosis
- ❑ Member has a definitive diagnosis of HLH as indicated by **ONE** of the following **(submit documentation)**:
  - ❑ A diagnosis of primary HLH based on identification of biallelic pathogenic gene variants from molecular genetic testing (e.g., PRF1, UNC13D, STX11, or STXBP2) or a family history consistent with primary HLH
  - ❑ At least **FIVE** of the following eight documented criteria:
    - ❑ Prolonged fever (≥101.3°F) > 7 days
    - ❑ Splenomegaly
    - ❑ Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9 g/dL, platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L)
    - ❑ Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L)
    - ❑ Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
    - ❑ Low or absent NK-cell activity
    - ❑ Ferritin ≥ 500mcg/L
    - ❑ Soluble CD25 (aka soluble IL-2Rα receptor) ≥ U/mL
- ❑ Member has active, primary disease that is refractory, recurrent, or progressive during treatment with conventional HLH therapy (e.g., etoposide + dexamethasone, cyclosporine A, anti-thymocyte globulin, etc.) unless patient is intolerant to conventional HLH therapy
- ❑ Member has **NOT** received hematopoietic stem cell transplant (HSCT) **[NOTE: Gamifant is being used as part of the induction or maintenance phase of stem cell transplant, and will be discontinued at the initiation of conditioning for stem cell transplant]**
- ❑ Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment
- ❑ Provider will monitor and consider prophylaxis in patients for Herpes Zoster, Pneumocystis Jirovecii, and fungal infections
- ❑ Member does **NOT** have an active infection, including clinically important localized infections that are favored by interferon-gamma neutralization (e.g., infections caused by mycobacteria, Histoplasma Capsulatum, etc.)
- ❑ Provider attests that the member will **NOT** be administered concurrently with live or live attenuated vaccines

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- ❑ Requested medication will be used in combination with dexamethasone **[NOTE: Patients currently on oral cyclosporine A, or intrathecal methotrexate and/or glucocorticoids may continue on therapy while treated with emapalumab]**

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 continues to meet criteria such as concomitant therapy requirements (not including prerequisite therapy), etc. identified in the initial criteria section above
- ❑ Member continues to require therapy for treatment of HLH (e.g., until HSCT is performed or unacceptable toxicity)
- ❑ Member has experienced disease improvement in HLH abnormalities as evidenced by **ONE** of the following:
  - ❑ Complete response defined as normalization of all HLH abnormalities (i.e., no fever, no splenomegaly, neutrophils > $1x10^9$/L, platelets > $100x10^9$/L, ferritin < 2,000 µg/L, fibrinogen > 1.50 g/L, D-dimer < 500 µg/L, normal CNS symptoms, no worsening of sCD25 > 2-fold baseline)
  - ❑ Partial response defined as normalization of ≥ 3 HLH abnormalities (including CNS abnormalities)
  - ❑ HLH improvement defined as improvement by at least 50% from baseline of ≥ 3 HLH clinical and laboratory criteria (see initial criteria section)
- ❑ Requested medication will be used in combination with dexamethasone **[NOTE: Patients currently on oral cyclosporine A, or intrathecal methotrexate and/or glucocorticoids may continue on therapy while treated with emapalumab]**
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., serious infections (including mycobacteria, Herpes Zoster virus, and Histoplasma Capsulatum), infusion-related reactions (including drug eruption, pyrexia, rash, erythema, and hyperhidrosis))
- ❑ Dose escalation requests are based on clinical and laboratory parameters being interpreted as an unsatisfactory response defined as at least **ONE** of the following (up to the maximum dose and frequency specified in the Dosage/Administration table below):

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Treatment Day	Gamifant Dose	Criteria for Dose Increase
Day 1	Starting Dose of 1 mg/kg	N/A; Initial
From Day 4 onwards	Increase to 3 mg/kg	Unsatisfactory improvement in clinical condition, as assessed by a healthcare provider **AND** at least one of the following: ▪ Fever – persistence or recurrence ▪ Platelet count ▪ If baseline < 50,000/mm^3 and without improvement to > 50,000/mm^3 ▪ If baseline > 50,000/mm^3 and less than 30% improvement ▪ If baseline > 100,000/mm^3 and decrease to < 100,000/mm^3 ▪ Neutrophil count ▪ If baseline < 500/mm^3 and without improvement to > 500/mm^3 ▪ If baseline > 500/mm^3 to 1,000/mm^3 and decrease to < 500/mm^3 ▪ If baseline 1,000/mm^3 to 1,500/mm^3 and decrease to < 1,000/mm^3 ▪ Ferritin (ng/mL) ▪ If baseline ≥ 3,000 ng/mL and < 20% decrease ▪ If baseline < 3,000 ng/mL and any increase to > 3,000 ng/mL ▪ Splenomegaly – any worsening ▪ Coagulopathy (both D-Dimer and Fibrinogen must apply) ▪ D-Dimer; if abnormal at baseline and no improvement ▪ Fibrinogen (mg/dL) ▪ If baseline levels ≤ 100 mg/dL and without improvement ▪ If baseline levels > 100 mg/dL and any decrease to < 100 mg/dL
From Day 7 onwards	Increase to 6 mg/kg	
From Day 10 onwards	Increase to 10 mg/kg	Assessment by a healthcare provider that based on initial signs of response, a further increase in Gamifant dose can be of benefit

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Medication being provided by (check applicable box below):

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

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

***Approved by Pharmacy and Therapeutics Committee:** 2/20/2020
REVISED/UPDATED: 10/15/2025