Updated: 07/2024
DMMA Approved: 07/2024

Request for Prior Authorization for Gamifant (emapalumab-lzsg)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Gamifant (emapalumab-lzsg) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Gamifant (emapalumab-lzsg) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of Primary (Familial) Hemophagocytic Lymphohistiocytosis (HLH) and the following criteria is met:

- Must be prescribed by or in consultation with a hematologist.
- Diagnosis must be confirmed by one of the following:
    - Molecular genetic testing confirms a genetic mutation known to cause HLH (ie. FHL2-PRF1, FHL3-UNC13D (MUNC 13-4), FHL4-STX11, FHL5-STXBP2 (UNC18B), Griscelli Syndrome type 2 (RAB27A), X-linked lymphoproliferative disorder 1 or 2 (SH2D1A or NLRC4))
    - Family history consistent with primary HLH
    - At least 5 of the following diagnostic criteria are present per HLH-2004 protocol and the American Histiocyte Society:
        - Fever
        - 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 (≥ 265 mg/dL) 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 ≥ 500 mcg/L
        - Elevations of soluble CD25 above age-adjusted, laboratory-specific normal levels (defined as > 2 SD from the mean)
- Must have evidence of active disease that is refractory, recurrent, or progressive during, or were intolerant of at least 2 conventional HLH therapy (ie. etoposide, dexamethasone, cyclosporine, anti-thymocyte globulin, methotrexate)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- **Initial Duration of Approval:** 8 weeks
- **Reauthorization criteria**
    - Documentation of positive clinical response
    - Documentation that hematopoietic stem cell transplant (HSCT) has been scheduled or is being planned
- **Reauthorization Duration of Approval:** 6 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

HIGHMARK HEALTH OPTIONS

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GAMIFANT (EMAPALUMAB-LZSG) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Does genetic testing confirm a genetic mutation known to cause HLH? ☐ Yes ☐ No

Is there a family history consistent with primary HLH? ☐ Yes ☐ No

Which of the following are present? Check all that apply:

- ☐ Fever
- ☐ Splenomegaly
- ☐ Low or absent NK-cell activity
- ☐ Ferritin ≥ 500 mcg/L
- ☐ Cytopenias affecting at least 2 of 3 lineages (Hgb, Plt, neutrophils)
- ☐ Hypertriglyceridemia (≥ 265 mg/dL) or hypofibrinogenemia (≤ 1.5 g/L)
- ☐ Hemophagocytosis in bone marrow, spleen, or lymph nodes with no malignancy
- ☐ Elevations of soluble CD25

What has been tried previously? Check all that apply:

- ☐ Etoposide
- ☐ Dexamethasone
- ☐ Cyclosporine
- ☐ Anti-thymocyte globulin
- ☐ Methotrexate
- ☐ Other: _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has there been a positive clinical response? ☐ Yes ☐ No

Has a stem cell transplant been scheduled or planned? ☐ Yes, date: _____ ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date