

Prior Authorization Criteria
Gamifant (emapalumab-lzsg)

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

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 (e.g. 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 [< 10 g/dL in infants < 4 weeks], platelets < $100 \times 10^9/L$, neutrophils < $1 \times 10^9/L$)
 - 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 a conventional HLH therapy (ie. etoposide with dexamethasone, 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**
 - Clinical documentation of positive clinical response involving the following clinical and laboratory parameters: Fever, splenomegaly, central nervous system symptoms, complete blood count, fibrinogen and/or D-dimer, ferritin, and soluble CD25 (also referred to as soluble interleukin-2 receptor) levels.
 - Documentation that hematopoietic stem cell transplant (HSCT) has been scheduled or is being planned
- **Reauthorization Duration of Approval:** 6 months



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Updated: 05/2021
PARP Approved: 06/2021

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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



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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 Gateway HealthSM Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

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

REQUESTED DRUG INFORMATION

Medication:	Strength:
Directions:	Quantity: Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE: _____	
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other	

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:
How was the diagnosis confirmed? <input type="checkbox"/> Genetic testing <input type="checkbox"/> Family history of primary HLH <input type="checkbox"/> Other (<i>describe below</i>)	
Please indicate all of the following that apply to the member:	
<input type="checkbox"/> Fever	<input type="checkbox"/> Cytopenias affecting 2 of 3 lineages (Hgb < 9, Plt < 100 x 10 ⁹ /L, Neutrophils < 1 x 10 ⁹ /L)
<input type="checkbox"/> Splenomegaly	<input type="checkbox"/> Hypertriglyceridemia (≥ 265 mg/dL) or hypofibrinogenemia (≤ 1.5 g/L)
<input type="checkbox"/> Low or no NK-cell activity	<input type="checkbox"/> Hemophagocytosis in bone marrow, spleen, or lymph nodes with no malignancy
<input type="checkbox"/> Ferritin ≥ 500 mcg/L	<input type="checkbox"/> Elevated CD25
Does the member have active disease that is refractory, recurrent, or progressive following conventional HLH therapy? <input type="checkbox"/> Yes (<i>list all previous therapy below</i>) <input type="checkbox"/> No (<i>please provide clinical rationale below</i>)	
Is a hematopoietic stem cell transplant (HSCT) scheduled or being planned? <input type="checkbox"/> Yes, date: _____ <input type="checkbox"/> No	

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Has there been a positive clinical response? <input type="checkbox"/> Yes, please describe below or provide chart documentation <input type="checkbox"/> No
Is a hematopoietic stem cell transplant (HSCT) scheduled or being planned? <input type="checkbox"/> Yes, date: _____ <input type="checkbox"/> No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date

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