HIGHMARK WHOLECARE

Updated: 07/2025
PARP Approved: 08/2025

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 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 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

Coverage may be provided with a diagnosis of Hemophagocytic Lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA) and the following criteria is met:

- Must be prescribed by or in consultation with a hematologist and/or rheumatologist
- Must meet all of the following American College of Rheumatology/EULAR criteria to confirm MAS:
  - Fever
  - Ferritin > 684 ng/ml
  - Two of the following:
    - Platelet ≤ 181 x $10^9$/L
    - Aspartate aminotransferase > 48 units/L
    - Triglycerides > 156 mg/dL
    - Fibrinogen ≤ 360 mg/dL
- Must have had an inadequate response or intolerance to glucocorticoids
- 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:** 2 months
- **Reauthorization criteria**
  - Documentation of positive clinical response
  - HLH/MAS symptoms are still present
- **Reauthorization Duration of Approval:** 2 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.

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 Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 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: | |
| 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: | |

## 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: |

**For Primary (Familial) Hemophagocytic Lymphohistiocytosis (HLH):**

How was the diagnosis confirmed? ☐ Genetic testing ☐ Family history of primary HLH ☐ Other *(describe below)*

Please indicate all of the following that apply to the member:

- ☐ Fever
- ☐ Splenomegaly
- ☐ Low or no NK-cell activity
- ☐ Ferritin ≥ 500 mcg/L
- ☐ Cytopenias affecting 2 of 3 lineages (Hgb < 9, Plt < 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 malignancy
- ☐ Elevated CD25

Does the member have active disease that is refractory, recurrent, or progressive following conventional HLH therapy?

☐ Yes *(list all previous therapy below)* ☐ No *(please provide clinical rationale below)*

Is a hematopoietic stem cell transplant (HSCT) scheduled or being planned? ☐ Yes, date: _____ ☐ No

**For HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease:**

Which of the following symptoms are present:

- ☐ Fever
- ☐ Ferritin ≥ 500 mcg/L
- ☐ Platelets < 181 x $10^9$/L
- ☐ Aspartate aminotransferase > 48 units/L
- ☐ Triglycerides > 156 mg/dL
- ☐ Fibrinogen ≤ 360 mg/dL

## CURRENT or PREVIOUS THERAPY

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

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| REAUTHORIZATION |
|---|
| Has there been a positive clinical response? ☐ Yes, please describe below or provide chart documentation ☐ No |
| **For Primary (Familial) HLH:**<br>Is a hematopoietic stem cell transplant (HSCT) scheduled or being planned? ☐ Yes, date: _____ ☐ No |
| **For HLH/MAS in known or suspected Still's disease:**<br>Which of the following symptoms are present to warrant ongoing therapy?<br>☐ Fever ☐ Aspartate aminotransferase > 48 units/L<br>☐ Ferritin ≥ 500 mcg/L ☐ Triglycerides > 156 mg/dL<br>☐ Platelets < 181 x $10^9$/L ☐ Fibrinogen ≤ 360 mg/dL |

| SUPPORTING INFORMATION or CLINICAL RATIONALE |
|---|
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| |
| |

| Prescribing Provider Signature | Date |
|---|---|
| | |