Familial hemophagocytic lymphohistiocytosis
Gamifant (emapalumab-lzsg) J9210
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ Documentation is provided that Patient has a diagnosis of active primary hemophagocytic lymphohistiocytosis (HLH) as confirmed by one of the following:

- ☐ Patient has a genetic mutation known to cause HLH; OR
- ☐ Patient has a family history consistent with primary HLH; OR
- ☐ Patient meets five of the following criteria:
  - ☐ Fever
  - ☐ Splenomegaly
  - ☐ Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9 g/dL (or < 10 g/dL in infants), platelets < 100 x 109/L, neutrophils < 1 x 109/L)
    Hypertriglyceridemia (fasting TG ≥ 265 mg/dL) and/or hypofibrinogenemia (fibrinogen ≤ 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
  - ☐ Soluble CD25 ≥ 2400 U/mL;

☐ Patient is using in combination with dexamethasone; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as etoposide, dexamethasone, or cyclosporine); AND
Patient is a candidate for hematopoietic stem cell transplant or has not received a successful hematopoietic stem cell transplant.

- Requests for Gamifant (emapalumab-lzsg) may NOT be approved for secondary or acquired HLH

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient has clinical response to treatment with Gamifant (improvement in initial clinical or laboratory parameters); AND

☐ Patient is experiencing residual active disease; AND

☐ Patient has not received a successful hematopoietic stem cell transplant; AND

☐ Dose has been titrated to the minimum dose and frequency necessary to achieve satisfactory improvement as defined by FDA labeling for Gamifant (emapalumab-lzsg).

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Familial Hemophagocytic Lymphohistiocytosis Drug PA

Drug Name(s):
GAMIFANT **EMAPALUMAB-LZSG**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
HLH related specialist

Coverage Duration:
Initial Approval will be for 6 months
Continuation will be approved for 12 months

FDA Indications:
Gamifant

- Familial hemophagocytic lymphohistiocytosis, Refractory, recurrent, or progressive disease or intolerance with conventional therapy

Off-Label Uses:
N/A

Age Restrictions:
N/A

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/31388E/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/BC4FCF/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932591&contentSetId=100&title=Emapalumab-lzsg&servicesTitle=Emapalumab-lzsg&brandName=Gamifant&UserMdxSearchTerm=Gamifant&=null#