

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Gamifant (emapalumab-lzsg)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Gamifant (emapalumab-lzsg) injection

APPROVAL CRITERIA

Requests for Gamifant (emapalumab-lzsg), may be approved if the following criteria are met:

- I. Individual has a diagnosis of active primary hemophagocytic lymphohistiocytosis (HLH) as confirmed by **one** of the following:
 - A. Individual has a genetic mutation known to cause HLH; **OR**
 - B. Individual has a family history consistent with primary HLH; **OR**
 - C. Individual meets **five** of the following criteria:
 1. Fever
 2. Splenomegaly
 3. 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)
 4. Hypertriglyceridemia (fasting TG ≥ 265 mg/dL) and/or hypofibrinogenemia (fibrinogen ≤ 1.5 g/L)
 5. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
 6. Low or absent NK-cell activity
 7. Ferritin ≥ 500 mcg/L
 8. Soluble CD25 ≥ 2400 U/mL;

AND

- II. Individual is using in combination with dexamethasone; **AND**
- III. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as etoposide, dexamethasone, or cyclosporine).

Requests for Gamifant (emapalumab-lzsg) may **not** be approved for the following:

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New Program Date 05/21/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0393-19

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Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	X

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- I. Individual has a diagnosis of secondary or acquired HLH.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 15, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Henter JI, Horne AC, et al. HLH-2004: Diagnostic and Therapeutic Guidelines for Hemophagocytic Lymphohistiocytosis. *Pediatr Blood Cancer* 2007;48:124–131.

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