Gamifant (emapalumab-lzsg)

Override(s)	Approval Duration
Prior Authorization	Initial requests: 3 months Continuation requests: 6 months

Medications
Gamifant (emapalumab-lzsg) injection

APPROVAL CRITERIA

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

I. Documentation is provided that 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 10^9/L, neutrophils < 1 x 10^9/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); **AND**

IV. Individual is a candidate for hematopoietic stem cell transplant or has not received a successful hematopoietic stem cell transplant.

Continuation requests for Gamifant (emapalumab-lzsg) may be approved if the following criterion is met:

I. Individual has clinical response to treatment with Gamifant (improvement in initial clinical or laboratory parameters); **AND**

II. Documentation is provided that individual is experiencing residual active disease; **AND**

III. Documentation is provided that individual has not received a successful hematopoietic stem cell transplant; **AND**

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

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

I. Individual has a diagnosis of secondary or acquired HLH; **OR**
II. Individual has not met all the above criteria or for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. 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: April 2, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; 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.