

**Gamifant (emapalumab-lzsg)  
Effective 4/1/2020**

|                              |   |                     |   |
|------------------------------|---|---------------------|---|
| <b>Plan</b>                  | <input checked="" type="checkbox"/> MassHealth<br><input checked="" type="checkbox"/> Commercial/Exchange | <b>Program Type</b> | <input checked="" type="checkbox"/> Prior Authorization<br><input type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Benefit</b>               | <input type="checkbox"/> Pharmacy Benefit<br><input checked="" type="checkbox"/> Medical Benefit (NLX)    |                     |   |
| <b>Specialty Limitations</b> |   |                     |   |
| <b>Contact Information</b>   | <b>Specialty Medications</b>  |                     |   |
|                              | All Plans   | Phone: 866-814-5506 | Fax: 866-249-6155   |
|                              | <b>Non-Specialty Medications</b>  |                     |   |
|                              | MassHealth  | Phone: 877-433-7643 | Fax: 866-255-7569   |
|                              | Commercial  | Phone: 800-294-5979 | Fax: 888-836-0730   |
|                              | Exchange  | Phone: 855-582-2022 | Fax: 855-245-2134   |
|                              | <b>Medical Specialty Medications (NLX)</b>  |                     |   |
|                              | All Plans   | Phone: 844-345-2803 | Fax: 844-851-0882   |
| <b>Exceptions</b>            | N/A   |                     |   |

### Overview

Gamifant is indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

### Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Gamifant excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member has a diagnosis primary HLH
2. Member has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy
3. Presence of at least 5 of the following:
  - a) Fever
  - b) Splenomegaly
  - c) Cytopenias (defined as 2 of the following: hemoglobin < 9 g/dL, platelets < 100 x 10<sup>9</sup>/L, neutrophils < 1 x 10<sup>9</sup>/L)
  - d) Hypertriglyceridemia (fasting triglyceride ≥ 265 mg/dL OR > 3mmol/L) or hypofibrinogenemia (≤ to 150 mg/dL)
  - e) Hemophagocytosis in bone marrow, spleen or lymph nodes, or liver with no evidence of malignancy
  - f) Low or absent natural killer (NK) cell activity
  - g) Ferritin ≥ 500 ng/mL



- h) Soluble CD25 (soluble IL-2 receptor alpha) level  $\geq$  2400 U/mL
- 4. Possible causes of secondary or acquired forms of HLH (e.g., autoimmune disease, persistent infection, malignancy, or loss of inhibitory immune mechanisms) have been ruled out.

### **Continuation of Therapy**

Reauthorization requires physician documentation of improvement of member's condition.

### **Limitations**

1. Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
  - a. If member has a positive test result or is at risk for TB, prophylactic treatment for TB must be initiated before starting therapy.
2. Initial approvals will be authorized 6 months
3. Reauthorizations will be authorized for 12 months

### **References**

1. Gamifant [package insert]. Waltham, MA: Sobi, Inc.; November 2018.
2. Henter JI, Horne A, Arico M et al. HLH-2004: diagnostic and therapeutic guidelines for hemophagocytic lymphohistiocytosis. *Pediatr Blood Cancer*. 2007;48:124-131.
3. Allen CE and McClain KL. *Hematology Am Soc Hematol Educ Program*. 2015;2015:177-82.
4. Janka, G.E. and E.M. Schneider, Modern management of children with haemophagocytic lymphohistiocytosis. *Br J Haematol*, 2004. 124(1): p. 4-14.

### **Review History**

11/20/2019: Reviewed P&T

11/25/2019: Reviewed and approved DCC

01/22/2020: Approved P&T Mtg

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