Mass General Brigham
Health Plan

Gamifant (emapalumab-lzsg)
Effective 04/01/2020

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	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 new to the plan 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 10^9/L, neutrophils < 1 x 10^9/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 ≥ 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.; June 2020.
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
09/21/2022: Reviewed at Sept P&T; Separated Comm/Exch vs MH policies; no clinical updates.