Medical Policy:

Gamifant® (emapalumab-lzsg) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.312	March 1, 2024	April 1, 2019

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

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Definitions

Gamifant, an anti-interferon gamma (IFN-γ) antibody, is indicated for the treatment of adult and pediatric patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Approve up to a maximum dose of 10 mg/kg by intravenous infusion, not more frequently than twice weekly (once every 3 to 4 days).

Max Units (per dose and over time) [HCPCS Unit]:

• 2300 billable units weekly

Guideline

I. INITIAL CRITERIA

1. **Hemophagocytic Lymphohistiocytosis, Primary:** Approve Gamifant for 6 months if the patient meets the following criteria (A, B, C, and D):
   A. Patient has a diagnosis of hemophagocytic lymphohistiocytosis determined by at least **ONE** of the following (i or ii):
      i. Patient has a molecular genetic diagnosis consistent with hemophagocytic lymphohistiocytosis; **OR**
      ii. Prior to treatment, the patient meets at least **FIVE** of the following diagnostic criteria at baseline (FIVE of a, b, c, d, e, f, g, or h):
         a. Fever ≥ 38.5° C; **OR**
         b. Splenomegaly; **OR**
         c. Cytopenias defined as at least **TWO** of the following (TWO of 1, 2, or 3):
            1. Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age); **OR**
            2. Platelets < 100 x 10^9/L; **OR**
            3. Neutrophils < 1.0 x 10^9/L; **OR**
         d. Patient meets **ONE** of the following (1 or 2):
            1. Fasting triglycerides ≥ 265 mg/dL; **OR**
            2. Fibrinogen ≤ 1.5 g/L; **OR**
         e. Hemophagocytosis in bone marrow, spleen, or lymph nodes; **OR**
         f. Low or absent natural killer cell activity (according to local laboratory reference); **OR**
         g. Ferritin ≥ 500 mcg/L; **OR**
         h. Soluble CD25 (i.e., soluble interleukin-2 receptor) ≥ 2,400 U/mL; **AND**
   B. Patient has tried at least **ONE** conventional therapy (e.g., etoposide, cyclosporine A, or anti-thymocyte globulin); **AND**
   C. According to the prescriber, the patient has experienced at least **ONE** of the following (i or ii):
      i. Refractory, recurrent, or progressive disease during conventional therapy (e.g., etoposide, cyclosporine A, or anti-thymocyte globulin); **OR**
      ii. Intolerance to conventional therapy (e.g., etoposide, cyclosporine A, or anti-thymocyte globulin); **AND**
   D. The medication is prescribed by or in consultation with a hematologist, oncologist, immunologist, transplant specialist, or physician who specializes in hemophagocytic lymphohistiocytosis or related disorders.

II. RENEWAL CRITERIA

1. Patient continues to meet Initial Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. (Examples of unacceptable toxicity include: serious infections (including mycobacteria, Herpes Zoster virus, and Histoplasma Capsulatum), infusion-related reactions (including drug eruption, pyrexia, rash, erythema, and hyperhidrosis), etc.; **AND**
3. Patient continues to require therapy for treatment of HLH; **AND**
4. Patient experienced a disease improvement in HLH abnormalities

Applicable Procedure Codes

Code	Description
J9210	emapalumab-lzsg, 1 mg

Applicable NDCs

Code	Description
72171-0505-01	Gamifant 50mg/10mL Solution
72171-0501-01	Gamifant 10mg/2mL Solution

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66658-0510-01	Gamifant 5mg/mL Solution

ICD-10 Diagnoses

Code	Description
D76.1	Hemophagocytic Lymphohistiocytosis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/1/2024	Annual Review: Updated dosing limits, added renewal criteria
EmblemHealth & ConnectiCare	04/04/2023	Transfer from CCUM Template to Medical CoBranded Template Retired MG.MM.PH.188
EmblemHealth & ConnectiCare	01/04/2023	Annual Revision: No criteria changes
EmblemHealth & ConnectiCare	12/22/2021	Annual Revision: No criteria changes

References

1. Gamifant® intravenous infusion [prescribing information]. Waltham, MA: Sobi; November 2018.

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