Mass General Brigham
Health Plan

Gamifant (emapalumab-lzsg)
Effective 07/01/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Gamifant (emapalumab-lzsg) is an interferon gamma (IFNγ) blocking antibody 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 reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication 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. Diagnosis primary hemophagocytic lymphohistiocytosis (HLH)
2. Prescriber is a specialist (e.g., hematologist and oncologist) or consult notes from a specialist are provided
3. **ONE** of the following:
    a. Molecular tests confirming diagnosis of primary HLH
    b. At least **five** of the following suggesting primary HLH:
        i. Fever
        ii. Splenomegaly
        iii. Cytopenias defined by 2 of the following:
            1. hemoglobin < 9 g/dL
            2. platelets < 100 x 10^9/L
            3. neutrophils < 1 x 10^9/L)
        iv. Hypertriglyceridemia (defined by fasting triglyceride ≥ 265 mg/dL OR > 3mmol/L) and/or hypofibrinogenemia (≤ to 150 mg/dL)
        v. Hemophagocytosis in bone marrow, spleen, or lymph nodes
        vi. Low or absent natural killer (NK) cell activity based on laboratory reference
        vii. Ferritin ≥ 500 mcg/L
        viii. Soluble CD25 (soluble IL-2 receptor alpha) level ≥ 2400 U/mL

4. Member has active disease
5. Member does not have active infections caused by specific pathogens favored by IFNγ neutralization (e.g., mycobacteria, Histoplasma Capsulatum, Shigella, salmonella, campylobacter, leishmanial infections)
6. Inadequate response, adverse reaction or contraindication to conventional HLH therapy (chemotherapy and/or systemic corticosteroids and/or immunosuppressive therapy) *(See Appendix)*
7. **ONE** of the following:
    a. Dexamethasone will be administered concurrently
    b. Clinical rationale for not using dexamethasone
8. **ONE** of the following:
    a. Anticipated HSCT (haematopoietic stem cell transplantation) date
    b. Member is not a candidate for HSCT
9. Appropriate dosing

Continuation of Therapy

Prescriber provides documentation of **ALL** of the following:

1. Positive response to therapy as evidenced by **ONE** of the following *(evaluate clinical parameters and laboratory values – see appendix for HLH abnormalities)*:
    a. Complete response: normalization of all HLH abnormalities
    b. Partial response: normalization of ≥ 3 HLH abnormalities
    c. HLH improvement: ≥ 3 HLH abnormalities improved by at least 50% from baseline
2. **ONE** of the following:
    a. Dexamethasone will be administered concurrently
    b. Clinical rationale for not using dexamethasone
3. **ONE** of the following:
    a. Anticipated HSCT date
    b. Member is not a candidate for HSCT

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.

Appendix

Conventional HLH Therapies Examples
Conventional HLH therapy regimens include, but are not limited to: 1. Etoposide and dexamethasone 2. Methotrexate and hydrocortisone 3. Anti-thymocyte globulin, corticosteroids, cyclosporine, and methotrexate 4. Etoposide, dexamethasone, and cyclosporine 5. Cyclophosphamide, vincristine, and prednisone 6. Cyclophosphamide, doxorubicin, vincristine, and prednisolone (CHOP) 7. Doxorubicin, etoposide, and methylprednisolone (DEP)
HLH Abnormalities and Normalization Values for Recertification
1. No presence of fever 2. No presence of splenomegaly 3. No presence of CNS symptoms 4. Platelets ≥ 100 x 10^9/L 5. Neutrophils ≥ 1 x 10^9/L

6. Ferritin < 2,000 mcg/L
7. Fibrinogen > 1.5 g/L
8. D-dimer < 500 mcg/mL
9. Soluble CD25 > 2-fold from baseline

References

1. Gamifant [package insert] Waltham (MA): Sobi Inc; 2024 Oct.
2. FDA approves first treatment specifically for patients with rare and life-threatening type of immune disease [press release on the Internet]. 2018 Nov 20 [cited 2022 Jan 26]. Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-specifically-patients-rare-and-life-threatening-type-immune-disease.
3. Hemophagocytic Lymphohistiocytosis (HLH) [database on the Internet]: National Organization of Rare Diseases; 2018 [cited 2022 Jan 26]. Available from: https://rarediseases.org/rare-diseases/hemophagocytic-lymphohistiocytosis/.
4. McClain JL. Treatment and prognosis of hemophagocytic lymphohistiocytosis. In Basow DS (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2020 May 11 [cited 2022 Jan 26]. Available from: http://www.utdol.com/utd/index.do.
5. Daver Naval, McClain K, Allen C, et al. A consensus review on malignancy-associated hemophagocytic lymphohistiocytosis in adults. Cancer. 2017 September 01; 123(17): 3229–3240.
6. Lehmberg K, Nichols KE, Henter JI, et al. Consensus recommendations for the diagnosis and management of hemophagocytic lymphohistiocytosis associated with malignancies. Haematologica. 2015 Aug;100(8):997-1004.
7. Locatelli F, Jordan MB, Allen C, Cesaro S, Rizzari C, Rao A, et al. Emapalumab in Children with Primary Hemophagocytic Lymphohistiocytosis N Engl J Med. 2020 May 7;382(19):1811-1822.
8. Gamifant (emapalumab-lzsg) formulary dossier. Sobi Inc, Data on file.

Review History

09/21/22 – Created for Sept P&T; matched MH UPPL.
07/10/24 – Reviewed and updated for P&T. Removed criteria requiring documentation of baseline clinical parameters and lab values as it was repetitive with criterion 3. Effective 8/12/24.
06/11/25 – Reviewed and updated for P&T. Part of annual UM review. Updated formatting and references. Effective 7/1/25