Gamifant® (emapalumab-lzsg)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

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

- 9250 billable units per 30 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Universal Criteria [1]

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Providers will monitor and consider prophylaxis in patients for Herpes Zoster, *Pneumocystis Jirovecii*, and fungal infections; **AND**
- Patient does not have an active infection, including clinically important localized infections that are favored by interferon-gamma neutralization (e.g., infections caused by mycobacteria, Histoplasma Capsulatum, etc.); **AND**
- Must not be administered concurrently with live or live attenuated vaccines; **AND**

Primary Hemophagocytic Lymphohistiocytosis (HLH) † Φ [1,3-7]

- Patient has a definitive diagnosis of HLH as indicated by the following:
  - Patient diagnosis of primary HLH based on identification of biallelic pathogenic gene variants from molecular genetic testing (e.g., *PRF1, UNC13D, STX11, or STXBP2)* or a family history consistent with primary HLH; **OR**

- Patient has at least FIVE of the following eight documented criteria:
  - Prolonged fever (> 7 days)
  - Splenomegaly
  - Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9 g/dL, platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L)
  - Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L)
  - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
  - Low or absent NK-cell activity
  - Ferritin ≥ 500 mcg/L
  - Soluble CD25 (aka soluble IL-2Rα receptor) ≥ 2400 U/mL; **AND**

- Patient has active, primary disease that is refractory, recurrent, or progressive during treatment with conventional HLH therapy (e.g., dexamethasone, etoposide, cyclosporine A, anti-thymocyte globulin, etc.) unless patient is intolerant to conventional HLH therapy; **AND**
- Patient has NOT received hematopoietic stem cell transplant (HSCT)*****; **AND**
- Used in combination with dexamethasone (*Note: Patients currently on oral cyclosporine A, or intrathecal methotrexate and/or glucocorticoids may continue on therapy while treated with emapalumab)*

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS) † Φ [1]

- Patient has a definitive diagnosis of HLH/MAS as indicated by BOTH of the following:
  - Ferritin >684 ng/mL; **AND**
  - At least 2 of the following:
    - Platelet count ≤181×10^9/L
    - AST >48 U/L
    - Triglycerides >156 mg/dL
    - Fibrinogen levels ≤360 mg/dL; **AND**
- Patient has known or suspected diagnosis of Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA) or Adult Onset Still's Disease (AOSD); **AND**
- Patient has had an inadequate response or intolerance to high-dose intravenous (IV) glucocorticoids OR has experience recurrent MAS

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), etc. identified in section III; **AND**
- 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**
- Patient is receiving ongoing monitoring for adenovirus, EBV, and CMV viruses as clinically indicated; **AND**

Primary Hemophagocytic Lymphohistiocytosis (HLH) [1,4,5]

- Patient continues to require therapy for treatment of HLH (e.g., until HSCT is performed or unacceptable toxicity); **AND**
- Patient experienced a disease improvement in HLH abnormalities as evidenced by one of the following:
  - Complete response defined as normalization of all HLH abnormalities (i.e., no fever, no splenomegaly, neutrophils > $1x10^9$/L, platelets > $100x10^9$/L, ferritin < 2,000 µg/L, fibrinogen > 1.50 g/L, D-dimer < 500 µg/L, normal CNS symptoms, no worsening of sCD25 > 2-fold baseline); **OR**
  - Partial response defined as normalization of ≥ 3 HLH abnormalities (including CNS abnormalities); **OR**
  - HLH improvement defined as improvement by at least 50% from baseline of ≥ 3 HLH clinical and laboratory criteria (including CNS involvement); **OR**
- Dose escalation (up to the maximum dose and frequency specified in the Dosage/Administration table below) requests based on clinical and laboratory parameters being interpreted as an unsatisfactory response are defined as at least ONE of the following:
  - Fever – persistence or recurrence
  - Platelet count
    - If baseline < 50,000/mm^3 and no improvement to >50,000/mm^3
    - If baseline > 50,000/mm^3 and less than 30% improvement
    - If baseline > 100,000/mm^3 and decrease to < 100,000/mm^3
  - Neutrophil count
    - If baseline < 500/mm^3 and no improvement to > 500/mm^3

- If baseline > 500 -1000/mm^3 and decrease to < 500/mm^3
- If baseline 1000-1500/mm^3 and decrease to < 1000/mm^3

- Ferritin (ng/mL)
  - If baseline ≥ 3000 ng/mL and < 20% decrease
  - If baseline < 3000 ng/mL and any increase to > 3000 ng/mL
- Splenomegaly – any worsening
- Coagulopathy (both D-dimer and fibrinogen must apply)
  - D-Dimer
    - If abnormal at baseline and no improvement
  - Fibrinogen (mg/dL)
    - If baseline levels ≤ 100 mg/dL and no improvement
    - If baseline levels > 100 mg/dL and any decrease to < 100 mg/dL

**Patients should be evaluated for HSCT when a high-risk of relapse and a high-risk of mortality exists (e.g., homozygous or compound heterozygous HLH mutations exists, lack of response to initial HLH therapy, central nervous system involvement, and incurable hematologic malignancy).*

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS) [1]

- Patient continues to require therapy for treatment of HLH; **AND**
  - Patient experienced a complete response (CR) as evidenced by the following:
    - Clinical resolution of MAS signs and symptoms (a visual analogue scale (VAS), of ≤1 cm [range 0 to 10 cm]); **AND**
    - The following 7 laboratory parameter endpoints:
      - WBC count and platelet count above the lower limit of normal (LLN); **AND**
      - LDH, AST and ALT below 1.5 times the upper limit of normal (ULN); **AND**
      - Fibrinogen >100 mg/dL; **AND**
      - Ferritin levels decreased ≥80% from values at screening or baseline (whichever initial value was higher) or < 2000 ng/mL, whichever was lower; **OR**
  - Patient has had unsatisfactory improvement in clinical condition, as assessed by a healthcare provider and requires dose escalation (up to the maximum dose and frequency specified in the Dosage/Administration table below)

V. Dosage/Administration [1]

Indication	Dose
Primary HLH	Administer initial doses of 1 mg/kg, intravenously over one hour, twice per week (every three to four days). Titrate doses up to 10 mg/kg as follows:

<table>
<tr><td></td><td>
– From Day 4 onwards, if an unsatisfactory improvement in clinical condition is assessed by the healthcare provider (see criteria in section IV), increase to 3 mg/kg.
– From day 7 and onwards, if an unsatisfactory improvement in clinical condition is assessed by the healthcare provider on the 3 mg/kg dose, increase to 6 mg/kg.
– From day 10 and onwards, if an unsatisfactory improvement in clinical condition is assessed by the healthcare provider on the 6 mg/kg dose, increase to 10 mg/kg.
– <u>Note:</u>
○ For patients who are not receiving baseline dexamethasone treatment, begin dexamethasone at a daily dose of at least 5 mg/m^2 to 10 mg/m^2 the day before Gamifant treatment begins.
○ For patients who were receiving baseline dexamethasone, they may continue their regular dose provided the dose is at least 5 mg/m2.
○ Dexamethasone can be tapered according to the judgment of the treating physician
</td></tr>
<tr><td>HLH/MAS</td><td>
Administer intravenously over one hour according to the dosage schedule in the table below.
<table>
<tr><th>Treatment Day</th><th>Gamifant Dosage</th></tr>
<tr><td>Day 1</td><td>6 mg/kg</td></tr>
<tr><td>Days 4 to 16</td><td>3 mg/kg every 3 days for 5 doses</td></tr>
<tr><td>From Day 19 onward</td><td>3 mg/kg twice per week (i.e., every 3 to 4 days)</td></tr>
</table>
– Discontinue Gamifant when patient no longer requires therapy for the treatment of HLH/MAS.
– If unsatisfactory improvement in clinical condition, as assessed by a healthcare provider, the dose and frequency of may be increased to:
○ Maximum cumulative dose of 10 mg/kg over 3 days
○ Frequency of every 2 days or once daily
– After the patient's clinical condition has improved, consider decreasing the dose to the previous level and assess whether clinical response is maintained.
– If the clinical condition is not stabilized while receiving the maximum dosage, consider discontinuing treatment.
</td></tr>
<tr><td colspan="2">– <u>NOTE</u>: Discontinue when a patient no longer requires therapy for the treatment of Primary HLH or HLH/MAS.</td></tr>
</table>

VI. Billing Code/Availability Information

HCPCS Code:

- J9210 − Injection, emapalumab-lzsg, 1 mg; 1 billable unit = 1 mg

NDC:

- Gamifant 10 mg/2 mL single-dose vial: 66658-0501-xx
- Gamifant 50 mg/10 mL single-dose vial: 66658-0505-xx
- Gamifant 100 mg/20 mL single-dose vial: 66658-0510-xx
- Gamifant 50 mg/2 mL single-dose vial: 66658-0522-xx
- Gamifant 100 mg/4 mL single-dose vial: 66658-0523-xx
- Gamifant 250 mg/10 mL single-dose vial: 66658-0524-xx

- Gamifant 500 mg/20 mL single-dose vial: 66658-0525-xx

VII. References

1. Gamifant [package insert]. Waltham, MA; Sobi, Inc., June 2025. Accessed July 2025.
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11. Hines MR, von Bahr Greenwood T, Beutel G, et al. Consensus-Based Guidelines for the Recognition, Diagnosis, and Management of Hemophagocytic Lymphohistiocytosis in Critically Ill Children and Adults. Crit Care Med. 2022 May 1;50(5):860-872. doi: 10.1097/CCM.0000000000005361. Epub 2021 Oct 5. PMID: 34605776.
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13. Wu, Y., Sun, X., Kang, K. et al. Hemophagocytic lymphohistiocytosis: current treatment advances, emerging targeted therapy and underlying mechanisms. J Hematol Oncol 17, 106 (2024). https://doi.org/10.1186/s13045-024-01621-x.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D76.1	Hemophagocytic lymphohistiocytosis
D89.40	Mast cell activation, unspecified
D89.49	Other mast cell activation disorder
M06.1	Adult-onset Still's disease
M08.0A	Unspecified juvenile rheumatoid arthritis, other specified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee

M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.4A	Pauciarticular juvenile rheumatoid arthritis, other specified site
M08.411	Pauciarticular juvenile rheumatoid arthritis, right shoulder

M08.412	Pauciarticular juvenile rheumatoid arthritis, left shoulder
M08.419	Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder
M08.421	Pauciarticular juvenile rheumatoid arthritis, right elbow
M08.422	Pauciarticular juvenile rheumatoid arthritis, left elbow
M08.429	Pauciarticular juvenile rheumatoid arthritis, unspecified elbow
M08.431	Pauciarticular juvenile rheumatoid arthritis, right wrist
M08.432	Pauciarticular juvenile rheumatoid arthritis, left wrist
M08.439	Pauciarticular juvenile rheumatoid arthritis, unspecified wrist
M08.441	Pauciarticular juvenile rheumatoid arthritis, right hand
M08.442	Pauciarticular juvenile rheumatoid arthritis, left hand
M08.449	Pauciarticular juvenile rheumatoid arthritis, unspecified hand
M08.451	Pauciarticular juvenile rheumatoid arthritis, right hip
M08.452	Pauciarticular juvenile rheumatoid arthritis, left hip
M08.459	Pauciarticular juvenile rheumatoid arthritis, unspecified hip
M08.461	Pauciarticular juvenile rheumatoid arthritis, right knee
M08.462	Pauciarticular juvenile rheumatoid arthritis, left knee
M08.469	Pauciarticular juvenile rheumatoid arthritis, unspecified knee
M08.471	Pauciarticular juvenile rheumatoid arthritis, right ankle and foot
M08.472	Pauciarticular juvenile rheumatoid arthritis, left ankle and foot
M08.479	Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot
M08.48	Pauciarticular juvenile rheumatoid arthritis, vertebrae
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand

M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, other specified site
M08.89	Other juvenile arthritis, multiple sites
M08.9A	Juvenile arthritis, unspecified, other specified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot

M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC