

Summary of Relevant Codes*

^{*}This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. The hospital, pharmacy, or healthcare provider is responsible for determining the appropriate codes, coverage, and payment for individual patients. Sobi, Inc. does not guarantee third-party coverage, or payment, or reimbursement for denied claims.



Indications and Important Safety Information

INDICATIONS

Gamifant (emapalumab-lzsg) is an interferon gamma (IFNy)-neutralizing 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.
- HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

IMPORTANT SAFETY INFORMATION Infections

Gamifant may increase the risk of fatal and serious infections with pathogens including mycobacteria, herpes zoster virus, and histoplasma capsulatum. Do not administer Gamifant in patients with these infections until appropriate treatment has been initiated.

In patients with primary HLH receiving Gamifant in clinical trials, serious infections such as sepsis, pneumonia, bacteremia, disseminated histoplasmosis, necrotizing fasciitis, viral infections, and perforated appendicitis were observed in 32% of patients.

In patients with HLH/MAS in Still's disease receiving Gamifant in clinical trials, serious infections such as pneumonia, cytomegalovirus infection, cytomegalovirus infection reactivation, and sepsis were observed in 13% of patients.

Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating Gamifant. Administer tuberculosis prophylaxis to patients at risk for tuberculosis or known to have a positive purified protein derivative (PPD) test result.

Consider prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infection while receiving Gamifant. Employ surveillance testing during treatment with Gamifant

Closely monitor patients receiving Gamifant for signs or symptoms of infection, promptly initiate a complete diagnostic workup appropriate for an immunocompromised patient, and initiate appropriate antimicrobial therapy.

Increased Risk of Infection With Use of Live Vaccines

Do not administer live or live attenuated vaccines to patients receiving Gamifant and for at least 4 weeks after the last dose of Gamifant. The safety of immunization with live vaccines during or following Gamifant therapy has not been studied.

Infusion-Related Reactions

Infusion-related reactions in patients with primary HLH, including drug eruption, pyrexia, rash, erythema, and hyperhidrosis, were reported with Gamifant treatment in 27% of patients. In one-third of these patients, the infusion-related reaction occurred during the first infusion.

Infusion-related reactions in patients with HLH/MAS in Still's disease, including pyrexia, headache, paresthesia, bone pain, pruritic rash, and peripheral coldness, were reported with Gamifant treatment in 13% of patients. Infusion-related reactions were reported as mild in 8% of patients and as moderate in 5% of patients.

Monitor patients for infusion-related reactions, which can be severe. Interrupt the infusion for infusion reactions and institute appropriate medical management before continuing infusion at a slower rate.

Adverse Reactions Primary HLH

Serious adverse reactions were reported in 53% of patients. The most common serious adverse reactions (≥3%) included infections, gastrointestinal hemorrhage, and multiple organ dysfunction. Fatal adverse reactions occurred in 2 (6%) of patients and included septic shock and gastrointestinal hemorrhage.

The most common adverse reactions were (≥10%) for Gamifant included infection (56%), hypertension (41%), infusion-related reactions (27%), pyrexia (24%), hypokalemia (15%), constipation (15%), rash (12%), abdominal pain (12%), CMV infection (12%), diarrhea (12%), lymphocytosis (12%), cough (12%), irritability (12%), tachycardia (12%), and tachypnea (12%).

HLH/MAS

Serious adverse reactions were reported in 12 patients (31%), with the most common serious adverse reaction being pneumonia (5%). Fatal adverse reactions occurred in two patients (5%) and included multiple organ dysfunction and circulatory shock.

The most common adverse reactions (≥10%) for Gamifant included viral infection (44%), rash (21%), anemia (18%), leukopenia (15%), thrombosis (15%), bacterial infections (13%), headache (13%), hyperglycemia (13%), infusion-related reactions (13%), abdominal pain (10%), hypertension (10%), pyrexia (10%), and thrombocytopenia (10%).

<u>Click here</u> for full Prescribing Information for Gamifant.



Preparing for Administration of Gamifant® (emapalumab-lzsg)

NATIONAL DRUG CODE (NDC) NUMBERS FOR GAMIFANT¹

NDC Numbers	Description
66658-501-01	One 10 mg/2 mL (5 mg/mL) single-dose vial
66658-505-01	One 50 mg/10 mL (5 mg/mL) single-dose vial
66658-510-01	One 100 mg/20 mL (5 mg/mL) single-dose vial

ANCILLARY SUPPLIES REQUIRED FOR THE ADMINISTRATION OF GAMIFANT

Item	Specification
Gamma-irradiated or ethylene oxide sterilized, latex-free, polyvinyl chloride (PVC)-free syringes (depending	50 mL syringe
on volume)	20 mL syringe
Non DVC not votation infusion base (depending on votume)	150 mL infusion bag
Non-PVC polyolefin infusion bags (depending on volume)	250 mL infusion bag
Non-pyrogenic, low-protein binding filter	0.2 μm filter

For additional information regarding ancillary supplies, including item codes and material availability, contact McKesson at 877-625-2566 or visit **their website** to download the latest product guide.

IMPORTANT SAFETY INFORMATION

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Summary of Relevant Codes

INTERNATIONAL CLASSIFICATION OF DISEASES, TENTH REVISION, CLINICAL MODIFICATION (ICD-10-CM) DIAGNOSIS CODES²

ICD-10-CM Codes	Description		
D76.1	Hemophagocytic lymphohistiocytosis (HLH)		
D76.2	Hemophagocytic syndrome, infection-associated		
M06.1	Adult-onset Still's disease		
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites		
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site		
Social Determinants of Health Codes	Description		
Z55	Problems related to education and literacy		
Z 56	Problems related to employment and unemployment		
Z 57	Occupational exposure to risk factors		
Z59	Problems related to housing and economic circumstances*		
Z 60	Problems related to social environment		
Z62	Problems related to upbringing		
Z63	Other problems related to primary support group, including family circumstances		
Z64	Problems related to certain psychosocial circumstances		
Z65	Problems related to other psychosocial circumstances		

^{*}In 2025, the following codes were changed from nonCC to CC: Z59.10, Z59.11, Z59.12, Z59.19, Z59.811, Z59.812, and Z59.819.3 CC=complication or comorbidity.

IMPORTANT SAFETY INFORMATION (continued) Infections (continued)

In patients with HLH/MAS in Still's disease receiving Gamifant in clinical trials, serious infections such as pneumonia, cytomegalovirus infection, cytomegalovirus infection reactivation, and sepsis were observed in 13% of patients.

Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating Gamifant. Administer tuberculosis prophylaxis to patients at risk for tuberculosis or known to have a positive purified protein derivative (PPD) test result.



ENHANCED AMBULATORY PATIENT GROUP (EAPG) CODE4

EAPG Code	Description	
780	Other hematological diagnoses	

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODE FOR PRODUCT⁵

HCPCS Code	Description		
J9210	Injection, emapalumab-lzsg, 1 mg		

ADDITIONAL PROCEDURES⁵

HCPCS Code	Description
J1100	Injection, dexamethasone sodium phosphate, 1 mg
G0136	Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5-15 minutes

DIAGNOSIS-RELATED GROUP (DRG)/ALL PATIENT REFINED (APR)-DRG CODES

DRG Codes ⁶	Description	
814	Reticuloendothelial & immunity disorders W MCC (with major complications)	
815	Reticuloendothelial & immunity disorders W CC (with complications)	
816	Reticuloendothelial & immunity disorders W/O CC/MCC (without complications/major complications)	
Medicaid APR-DRG Codes ⁷	Description	
660-1-660-4	Major hematologic/immunologic diagnosis, except sickle cell crisis & coagulation	
663-1-663-4	Other anemias and disorders of blood and blood-forming organs	

IMPORTANT SAFETY INFORMATION (continued)

Infections (continued)

Consider prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infection while receiving Gamifant. Employ surveillance testing during treatment with Gamifant.

Closely monitor patients receiving Gamifant for signs or symptoms of infection, promptly initiate a complete diagnostic workup appropriate for an immunocompromised patient, and initiate appropriate antimicrobial therapy.



NEW TECHNOLOGY ADD-ON PAYMENT (NTAP) CODE EXAMPLES^{8,9}

ICD-10-PCS Codes	Description	
XW033MA*	Introduction of emapalumab-lzsg anti-IFNy monoclonal antibody into peripheral vein, percutaneous approach, new technology group 10	
XW043MA*	Introduction of emapalumab-lzsg anti-IFNy monoclonal antibody into centra vein, percutaneous approach, new technology group 10	

^{*}NTAP application is pending with an expected effective date of October 2026.

CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODE EXAMPLES¹⁰

Procedure Type	CPT® Code	Indications for Testing	
Administration	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	
Monitoring or Treatment Observation Codes			
Platelet counts	85049	Platelet, automated	
White blood cell count (WBC) and differential	85004 85048	Blood count; automated differential WBC count Leukocyte (WBC), automated	
Ferritin	82728	Ferritin	
Coagulopathy (D-dimer or fibrinogen)	85610	Monitoring - Prothrombin time	
	85730	Monitoring - Partial thromboplastin time (PTT); plasma or whole blood Lab test	
	85379	Monitoring – D-dimer Lab test	
	85384	Fibrinogen; activity Lab test	

ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; IFNy=interferon gamma.

IMPORTANT SAFETY INFORMATION (continued) Increased Risk of Infection With Use of Live Vaccines

Do not administer live or live attenuated vaccines to patients receiving Gamifant and for at least 4 weeks after the last dose of Gamifant. The safety of immunization with live vaccines during or following Gamifant therapy has not been studied.



CPT® CODE EXAMPLES¹⁰ (continued)

Monitoring or Treatment Observation Codes (continued)		
Splenomegaly	76700	Ultrasound abdomen
	74160	Computerized tomography (CT) scan of the abdomen with contrast
	74150	CT scan of the abdomen without contrast
Fever (WBC)	85025	Complete blood count (CBC) with differential
	85027	CBC without differential
Tuberculosis	86480	Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response
	86481	Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T cells in cell suspension
	86580	Skin test for tuberculosis, intradermal
Herpes Zoster	87290	Varicella zoster virus
Adenovirus	87798	Amplified probe technique, each organism
Epstein-Barr virus (EBV)	86664	EBV nuclear antigen
Cytomegalovirus (CMV)	86644	CMV
	86645	CMV, immunoglobulin M
Soluble interleukin 2 (sIL-2)	83520	Quantitative, no otherwise specified Immunoassay

IMPORTANT SAFETY INFORMATION (continued)

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CPT® CODE EXAMPLES¹0 (continued)

Monitoring or Treatment Observation Codes (continued)		
Chemokine (C-X-C motif) ligand 9 (CXCL9)	83520	Quantitative, no otherwise specified Immunoassay
Natural killer cells function	88184 88185	Flow cytometry analysis: cell surface, cytoplasmic or nuclear markers, and additional markers
Lipid panel test	80061	Lipid panel
Triglyceride	84478	Triglycerides
Cerebrospinal fluid protein	84157	Other source (eg, synovial fluid, cerebrospinal fluid)
Magnetic resonance imaging (MRI)	70551 70552 70553	Magnetic resonance imaging, brain (including brain stem), with or without contrast material
Lymph node biopsy	38500 38505	Biopsy or excision of lymph node(s)

Genetic Testing		
Genetic testing	81402 81403 81404 81405 81406 81443 81479	HLH genetic analysis with molecular pathology procedure

IMPORTANT SAFETY INFORMATION (continued)

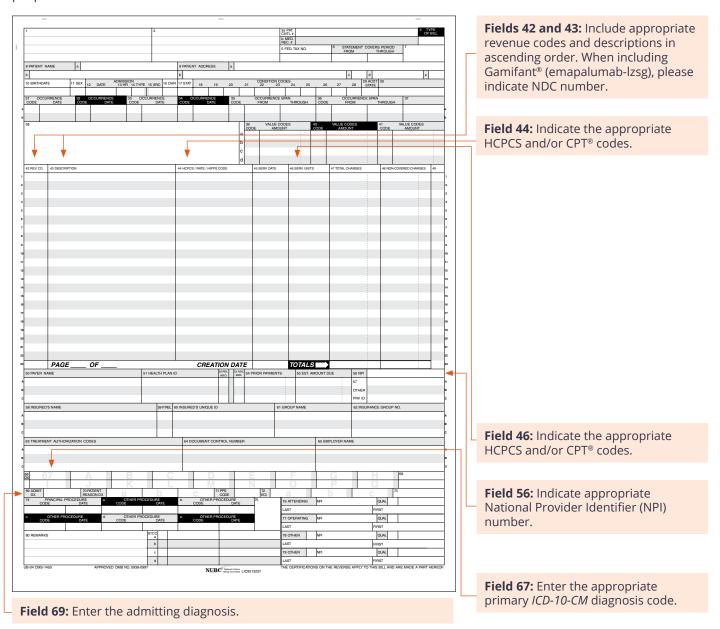
Infusion-Related Reactions (continued)

Infusion-related reactions in patients with HLH/MAS in Still's disease, including pyrexia, headache, paresthesia, bone pain, pruritic rash, and peripheral coldness, were reported with Gamifant treatment in 13% of patients. Infusion-related reactions were reported as mild in 8% of patients and as moderate in 5% of patients.



Sample Centers for Medicare & Medicaid Services (CMS) 1450/UB-04 Form

The CMS-1450, also known as the UB-04, form is used to bill for services at institutions such as hospitals and outpatient facilities.¹¹ However, providers should check with commercial and government payers to ensure the proper claim form is used.



IMPORTANT SAFETY INFORMATION (continued)

Infusion-Related Reactions (continued)

Monitor patients for infusion-related reactions, which can be severe. Interrupt the infusion for infusion reactions and institute appropriate medical management before continuing infusion at a slower rate.



REFERENCES:

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- 3. Centers for Medicare & Medicaid Services. Department of Health and Human Services. Medicare and Medicaid programs and the Children's Health Insurance Program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and policy changes and fiscal year 2025 rates; quality programs requirements; and other policy changes. Federal Register. 2024;89(167):68986-70046.
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- 5. Alpha-Numeric HCPCS 2025. Centers for Medicare & Medicaid Services website. Updated May 6, 2025. Accessed May 7, 2025. https://www.cms.gov/files/zip/july-2025-alpha-numeric-hcpcs-file.zip
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Click here for full Prescribing Information for Gamifant.

For statutory pricing disclosures, please <u>click here</u> for more information.

