

Summary of Relevant Codes*

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Indication and Important Safety Information

Indication

Gamifant® (emapalumab-Izsg) is an interferon gamma (IFNy)-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.

Important Safety Information

Infections

Before initiating Gamifant, patients should be evaluated for infection, including latent tuberculosis (TB). Prophylaxis for TB should be administered to patients who are at risk for TB or known to have a positive purified protein derivative (PPD) test result or positive IFNy release assay.

During Gamifant treatment, patients should be monitored for TB, adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) every 2 weeks and as clinically indicated.

Patients should be administered prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infections prior to Gamifant administration.

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, 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.

Adverse Reactions

In the pivotal trial, the most commonly reported adverse reactions (≥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%).

Additional selected adverse reactions (all grades) that were reported in less than 10% of patients treated with Gamifant included vomiting, acute kidney injury, asthenia, bradycardia, dyspnea, gastrointestinal hemorrhage, epistaxis, and peripheral edema.

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





Summary of Relevant Codes

INTERNATIONAL CLASSIFICATION OF DISEASES, TENTH REVISION, CLINICAL MODIFICATION (ICD-10-CM) DIAGNOSIS CODE¹

ICD-10-CM Code	Description	
D76.1	Hemophagocytic lymphohistiocytosis (HLH)	

ENHANCED AMBULATORY PATIENT GROUP (EAPG) CODE²

EAPG Code	Description	
780	Other hematologic diagnoses	

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODE FOR PRODUCT³

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

NATIONAL DRUG CODE (NDC) NUMBERS⁴

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	

CONCOMITANT MEDICATION³

HCPCS Code	Description	
J1100	Dexamethasone sodium phosphate, 1 mg	





Summary of Relevant Codes (continued)

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

DRG Codes ⁵	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 ⁶	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

CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODE EXAMPLES

Procedure Type ⁷	CPT® Code	Indications for Testing	
Administration	96365	Therapeutic, prophylactic, and diagnostic injections and infusions	
Monitoring or Treatment Observation Codes			
Platelet counts	85049	Monitoring – Lab test	
White blood cell count (WBC) and differential	85004 85048	Monitoring – Lab test	
Ferritin	82728	Monitoring – Lab test	
	85610	Monitoring – prothrombin time/international normalized ratio (PT/INR) Lab test	
Coagulopathy	85730	Monitoring – activated partial thromboplastin time (APTT) Lab test	
(D-dimer or fibrinogen)	85379	Monitoring – D-dimer Lab test	
	85384	Monitoring – Fibrinogen Lab test	
Splenomegaly/ hepatomegaly	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	





Summary of Relevant Codes (continued)

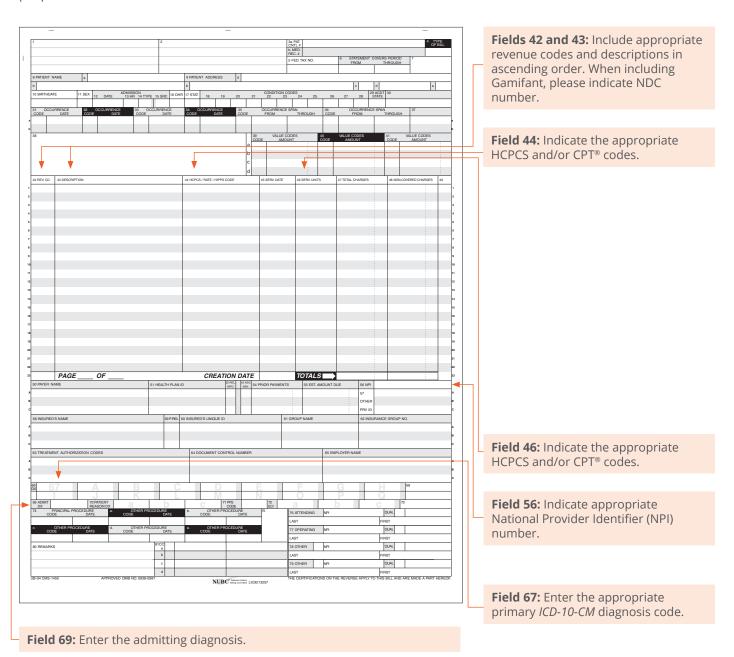
CPT® CODE EXAMPLES (continued)

Procedure Type ⁷⁻¹⁷	CPT® Code	Indications for Testing	
Tuberculosis	86580	Skin test for tuberculosis purified protein derivative (PPD)	
	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	
Adenovirus	87798	Adenovirus deoxyribonucleic acid (DNA), qualitative, real-time polymerase chain reaction (PCR)	
Epstein-Barr virus (EBV)	86664	EBV immunoassay	
Cytomegalovirus (CMV)	87252 87254	CMV, conventional and rapid, culture	
Soluble interleukin 2 (sIL-2)	83520	Monitoring – Lab test Immunoassay	
Chemokine (C-X-C motif) ligand 9 (CXCL9)	83520	Monitoring – Lab test Immunoassay	
Natural killer cells function	88184 88185	Flow cytometry analysis for immunophenotyping	
Lipid panel test	80061	Monitoring – Lab test	
Triglyceride	84478	Monitoring – Lab test	
Cerebrospinal fluid protein	84157	Monitoring – Lab test	
Magnetic resonance imaging (MRI)	70553	Diagnostic radiology (diagnostic imaging) procedures of the head and neck	
Lymph node biopsy	38500 38505	Biopsy or excision of lymph node(s)	
Genetic Testing			
Genetic testing	81443 81402 81403 81404 81405 81406 81479	HLH Genetic Analysis with molecular pathology procedure	



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.¹⁸ However, providers should check with commercial and government payers to ensure the proper claim form is used.







REFERENCES:

- 1. ICD-10-CM Code for hemophagocytic lymphohistiocytosis D76.1. Codify by AAPC website. Accessed March 25, 2024. https://www.aapc.com/codes/icd-10-codes/D76.1
- 2. 3M Health Information Systems. EAPG listing: effective October 1, 2018. Published August 23, 2018. February 21, 2024. https://dhcf.dc.gov/sites/default/files/dc/sites/dhcf/page_content/attachments/DC%20EAPG%20Relative%20Weights%20 Eff%2010-1-18%20DCO18023.pdf
- **3.** Alpha-Numeric HCPCS 2020. Centers for Medicare & Medicaid Services website. Accessed February 22, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File
- **4.** Gamifant [prescribing information]. Waltham, MA: Sobi, Inc; 2022.
- **5.** Diseases & disorders of blood, blood-forming organs, immunologic disorders DRG Code Range 799-816. Codify by AAPC website. Accessed April 4, 2023. https://www.aapc.com/codes/drg-codes-range/17
- **6.** Final APR-DRG Weights Effective July 1, 2018 (v34). New York State Department of Health website. Updated January 2, 2019. Accessed February 22, 2024. https://www.health.ny.gov/facilities/hospital/reimbursement/apr-drg/weights/2018-07-01_final_weights.htm
- 7. American Medical Association. CPT® 2020 Professional Edition. Chicago, IL: American Medical Association; 2020.
- **8.** Interleukin-2 soluble receptor α. Labcorp website. Accessed February 22, 2024. https://www.labcorp.com/tests/142455/interleukin-2-soluble-receptor
- 9. CXCL9 Level. Machaon Diagnostics website. Accessed February 22, 2024. https://www.machaondiagnostics.com/test/cxcl9-level
- **10.** Billing and coding: flow cytometry. Centers for Medicare & Medicaid Services website Accessed February 22, 2024. https://www.cms.gov/medicare-coverage-database/view/article aspx?articleid=56464&ver=28&keywordtype=starts &keyword=flow+cytometry&bc=0
- **11.** Lipid panel. Health lab website. Accessed February 22, 2024. https://www.healthlabtesting.com/Test%20Directory/Test%20Directory%20Item.aspx?itemGuid=0d2ff367-20f5-4002-a0f4-e02ad9c25243
- **12.** Triglycerides. Health lab website. Accessed February 22, 2024. https://healthlabtesting.com/Test%20Directory/Test%20Directory%20Item.aspx?itemGuid=ecba916e-f713-4ed4-9eba-a005bdeef13a
- **13.** Protein, cerebrospinal fluid. Health lab website. Accessed February 22, 2024. https://www.healthlabtesting.com/Test%20 Directory/Test%20Directory%20Item.aspx?itemGuid=a85270ff-4fca-4266-bac2-f6cf767a050b
- **14.** CPT® 70553, Under Diagnostic Radiology (Diagnostic Imaging) procedures of the head and neck. Codify by AAPC website. Accessed February 22, 2024. https://www.aapc.com/codes/cpt-codes/70553
- **15.** CPT® 38500, Under excision procedures on the lymph nodes and lymphatic channels. Codify by AAPC website. Accessed February 22, 2024. https://www.aapc.com/codes/cpt-codes/38500
- **16.** CPT® 38505, Under excision procedures on the lymph nodes and lymphatic channels. Codify by AAPC website. Accessed February 22, 2024. https://www.aapc.com/codes/cpt-codes/38505
- **17.** Billing and coding: molecular pathology and genetic testing. Centers for Medicare & Medicaid Services website. Accessed February 22, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58917
- **18.** What is the difference between HCFA-1500 (CMS 1500) and UB-04 (CMS 1450)? UB-04 Software website. Accessed March 18, 2024. https://ub04software.com/about/news-press/what-is-the-difference-between-hcfa-1500-cms-1500-and-ub-04-cms-1450

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