CYTOGAM®
Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IVIG)

Billing and Coding Guide

CYTOGAM® (Cytomegalovirus Immune Globulin Intravenous [Human] [CMV-IGIV])

Cytogam [Cytomegalovirus Immune Globulin Intravenous (Human)]

Cytogam® is an intravenous immunoglobulin containing standardized amount of antibody to cytomegalovirus.

Indication and Usage:

It is indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.

Important Safety Information:

Cytogam® is contraindicated in individuals with a history of a prior severe reaction associated with the administration of this or other human immunoglobulin preparations. Persons with selective immunoglobulin A deficiency have the potential for developing antibodies to immunoglobulin A and could have anaphylactic reactions to subsequent administration of blood products that contain immunoglobulin A, including Cytogam.

Please see full Prescribing Information for full prescribing details.

Introduction

Kamada Inc. has developed this billing and coding guide to support healthcare providers (HCPs) in understanding billing and coding for CYOTGAM.

This document is intended for informational purposes only and focuses on billing and coding for CYTOGAM. It is not a comprehensive description of potential coding requirements for CYTOGAM. As coding and coverage policies are subject to change, often without notice, it is the sole responsibility of the HCP to determine the appropriate coding, coverage, and reimbursement parameters for treating their patients.

The information provided in this guide should not be interpreted as a guarantee of coverage or reimbursement. HCPs must exercise their own judgment and due diligence in ensuring compliance with all applicable coding and billing requirements.

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Important Safety Information (cont.):

Immune Globulin Intravenous (Human) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Especially in such patients, IGIV products should be administered at the minimum concentrations available and the minimum rate of infusion practicable. Those containing sucrose as a stabilizer, like Cytogam, account for a disproportionate share of the total number of reports of renal dysfunction and acute renal failure when given at daily doses of 350 mg/kg or greater.

Coding Overview

Accurate reporting of billing codes is essential to ensure the codes correctly represent a patient's condition, the treatment provided, and the services rendered on the claim form submitted to the payer. All reported codes must be supported by corresponding medical record documentation.

The codes provided in this section may be applicable for reporting services associated with CYTOGAM treatment when administered in inpatient hospital settings, hospital outpatient departments (HOPDs), or independent infusion centers. The information below is for informational purposes and does not guarantee coverage or payment for CYTOGAM.

Coding for CYTOGAM

Payers typically recognize the following codes for reporting CYTOGAM and its administration on the appropriate claim form.

Healthcare Common Procedure Coding System (HCPCS)

HCPCS codes are used to report drugs and other procedures in the outpatient sites of care. The following product-specific HCPCS codes may be used to report CYTOGAM:

HCPCS code[1,a]	Description	Appropriate use
J0850	Injection, Cytomegalovirus Immune Globulin Intravenous (Human), per vial	One 50 mg/mL single-dose vial administered = 1 billing unit on the appropriate claim form

[a] HCPCS codes are not required on inpatient claims but may be reported for itemization purposes.

HCPCS Modifiers

Modifiers may be added to outpatient claims to provide payers with more information regarding services rendered. The following modifiers may be applicable to CYTOGAM:

Modifier[1]	Description	Appropriate use
JZ	Zero drug amount discarded/not administered to any patient	Report modifier JZ to indicate that there was no drug wastage (required for Medicare claims; check other payer requirements)
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	Report modifier TB when CYTOGAM is acquired through the 340B Drug Pricing Program (required for Medicare claims)

Important Safety Information (cont.):

During administration, the patient's vital signs should be monitored continuously, and careful observation made for any symptoms throughout the infusion. Epinephrine and diphenhydramine should be available for the treatment of an acute and anaphylactic reactions.

National Drug Code

Some payers may require the inclusion of National Drug Codes (NDCs) on claims, in addition to the product-specific HCPCS code. For claims reporting, the Health Insurance Portability and Accountability Act (HIPAA) mandates converting the 10-digit NDC to an 11-digit format by adding a leading "0" (zero), as needed, to achieve the 5-4-2 configuration.[2] It is important to verify payer-specific NDC reporting requirements. The NDCs used to report CYTOGAM in all sites of care are below:

10-digit NDC[3]	11-digit NDC	Description
49591-532-51	49591-**0**532-51	One carton containing one 50 mg/mL in a single-dose vial
49591-532-50	49591-**0**532-50	One 50 mg/mL single-dose vial

The NDC is typically preceded by the NDC qualifier "N4" on claims. When required by payers, report "ML" as the unit of measure with the appropriate NDC quantity. Check payer reporting requirements.

Current Procedural Terminology (CPT) Codes

CPT codes report medical services and procedures performed by HCPs on outpatient claims. Procedure codes that may be applicable to the administration of CYTOGAM include:

CPT code[4,a]	Description	Appropriate use
90291	Cytomegalovirus immune globulin (CMV-IgIV), human, for intravenous use	Report this code with the appropriate administration code in addition to the HCPCS code
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	This code may be used for CYTOGAM infusion, initial 90 minutes
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	This code may be used for CYTOGAM infusion intervals greater than 30 minutes beyond 1-hour increments (ie, infusion must run at least 91 minutes)

Key: HCPCS – Healthcare Common Procedure Coding System.

[a] CPT codes are not required on inpatient claims but may be reported for itemization purposes.

Important Safety Information (cont.):

Increases in serum creatinine and blood urea nitrogen (BUN) have been observed as soon as one to two days following IGIV infusion. Progression to oliguria or anuria requiring dialysis has been observed.

Immune Globulin Intravenous (Human) products can contain blood group antibodies, which may act as hemolysins and induce in vivo coating of red blood cells with immunoglobulin, causing a positive direct antiglobulin reaction and, rarely, hemolysis.

Revenue Codes

Revenue codes are used by sites of care that bill on the CMS-1450 (UB-04) claim form to identify the department in which services were provided, the types of services provided, and the supplies used. The following revenue codes may be used to report CYTOGAM and the intravenous infusion:

Item	Revenue code[5,a]	Description	Site of care
CYTOGAM	0258	Pharmacy, IV solutions	Inpatient
	0636	Drugs requiring detailed coding	HOPD
Intravenous infusion	0260	IV Therapy, general	Inpatient and HOPD
	0510	Clinic, general	HOPD

Key: HOPD – hospital outpatient department; IV – intravenous.

[a] Other revenue codes may apply.

Diagnosis Codes

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes report the patient-specific diagnosis documented in the medical record in all sites of care. The following ICD-10-CM codes may be applicable to CYTOGAM:

ICD-10-CM[6]	Description	Appropriate use
Inpatient infusion		
The ICD-10-CM code will vary by individual patient condition and reason for transplant		
Outpatient infusion		
Z48.21	Encounter for aftercare following heart transplant	The appropriate Z48.2[a] code may be used as the primary reason for an outpatient CYTOGAM infusion. They may be used for patients who have already received a transplant but who are receiving aftercare or prophylactic care[7]
Z48.22	Encounter for aftercare following kidney transplant	
Z48.23	Encounter for aftercare following liver transplant	
Z48.24	Encounter for aftercare following lung transplant	
Z48.280	Encounter for aftercare following heart-lung transplant	
Z48.298	Encounter for aftercare following other organ transplant	
Z94.0	Kidney transplant status	The appropriate Z94.[a] code may be used as a secondary code for an outpatient CYTOGAM infusion
Z94.1	Heart transplant status	
Z94.2	Lung transplant status	
Z94.3	Heart and lungs transplant status	
Z94.4	Liver transplant status	
Z94.83	Pancreas transplant status	

[a] Indicates that an additional character(s) is required to complete the valid code.

Important Safety Information (cont.):

Thrombotic events have been reported in association with IGIV. Patients at risk may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, and/or known or suspected hyperviscosity. The potential risks and benefits of IGIV should be weighed against those of alternative therapies for all patients for whom IGIV administration is being considered. Baseline assessment of blood viscosity should be considered in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies.

Medicare Severity – Diagnosis-Related Groups (MS-DRGs)

Medicare classifies each hospital inpatient stay according to the patient's main diagnosis, secondary diagnoses, procedures performed, and other factors; and then assigns the case to an MS-DRG. The MS-DRGs listed below may be applicable to inpatient administration of CYTOGAM:

MS-DRG[8]	Description	Appropriate use
001	Heart transplant or implant of heart assist system with MCC	The MS-DRG will vary by individual patient and the type of transplant
002	Heart transplant or implant of heart assist system without MCC	
005	Liver transplant with MCC or intestinal transplant	
006	Liver transplant without MCC	
007	Lung transplant	
008	Simultaneous pancreas and kidney transplant	
010	Pancreas transplant	
019	Simultaneous pancreas and kidney transplant with hemodialysis	
650	Kidney transplant with hemodialysis with MCC	
651	Kidney transplant with hemodialysis without MCC	
652	Kidney transplant	

Key: MCC – major comorbid condition; MS-DRG – Medicare Severity – Diagnosis-Related Groups.

Important Safety Information (cont.):

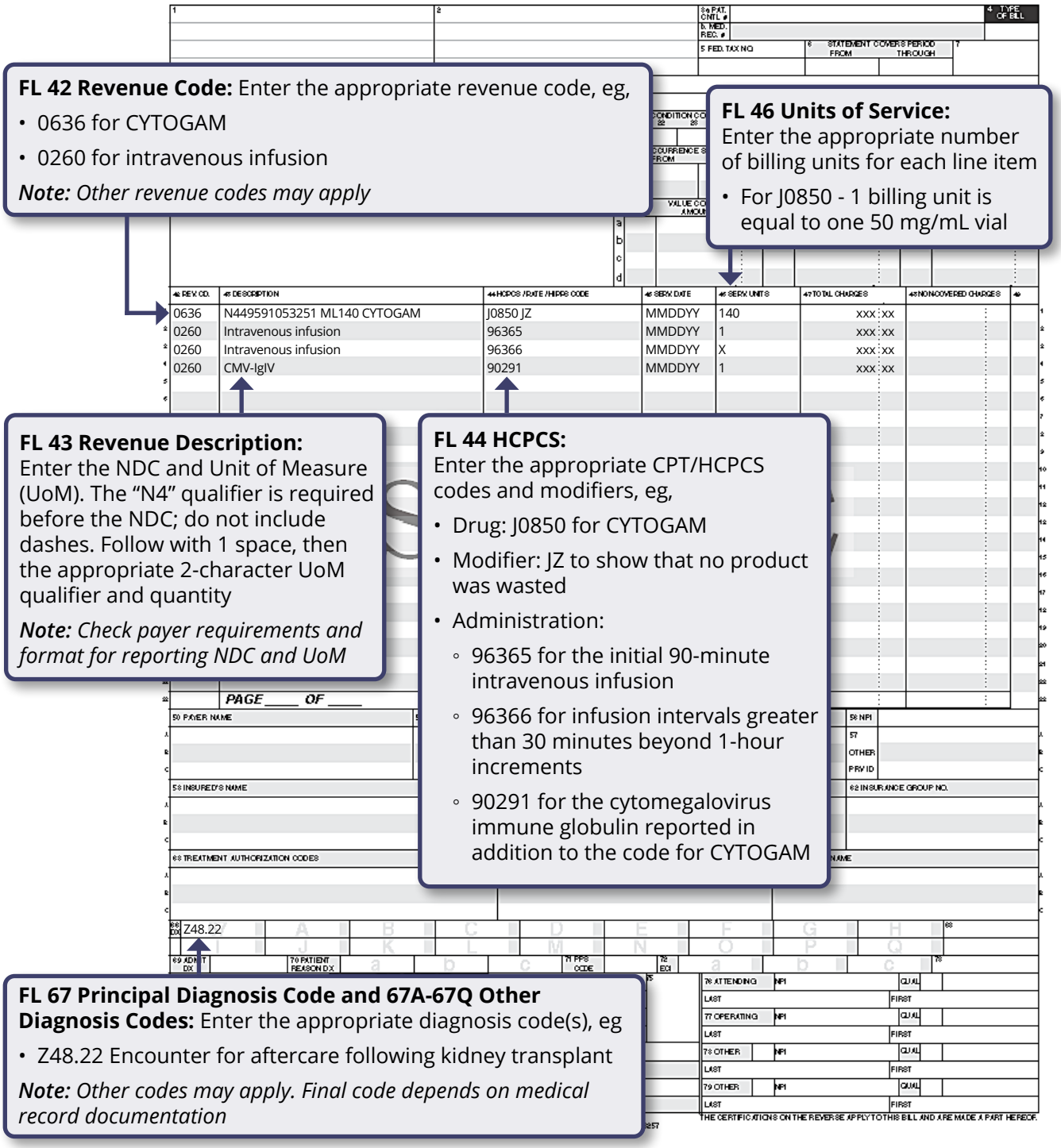
Cytogam® is derived from human plasma. As with all plasma-derived products, the risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

Minor reactions, such as flushing, chills, muscle cramps, back pain, fever, nausea, vomiting, arthralgia, and wheezing, were the most frequent adverse reactions observed during the clinical trials for Cytogam.

Sample Claim Form: CMS-1450 (UB-04) Hospital Outpatient Department

This sample claim form is intended as a reference for the billing and coding of CYTOGAM. This form is not intended to be directive, and the use of the recommended codes does not guarantee reimbursement. Hospitals may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice, patients, and services rendered.

The following is an example of a 70 kg patient receiving a 7,000 mg intravenous infusion of CYTOGAM within 4 weeks post kidney transplant.



FL 42 Revenue Code: Enter the appropriate revenue code, eg,

- 0636 for CYTOGAM
- 0260 for intravenous infusion

Note: *Other revenue codes may apply*

FL 46 Units of Service: Enter the appropriate number of billing units for each line item

- For J0850 - 1 billing unit is equal to one 50 mg/mL vial

FL 43 Revenue Description: Enter the NDC and Unit of Measure (UoM). The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UoM qualifier and quantity

Note: *Check payer requirements and format for reporting NDC and UoM*

FL 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, eg,

- Drug: J0850 for CYTOGAM
- Modifier: JZ to show that no product was wasted
- Administration:
  - 96365 for the initial 90-minute intravenous infusion
  - 96366 for infusion intervals greater than 30 minutes beyond 1-hour increments
  - 90291 for the cytomegalovirus immune globulin reported in addition to the code for CYTOGAM

FL 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code(s), eg

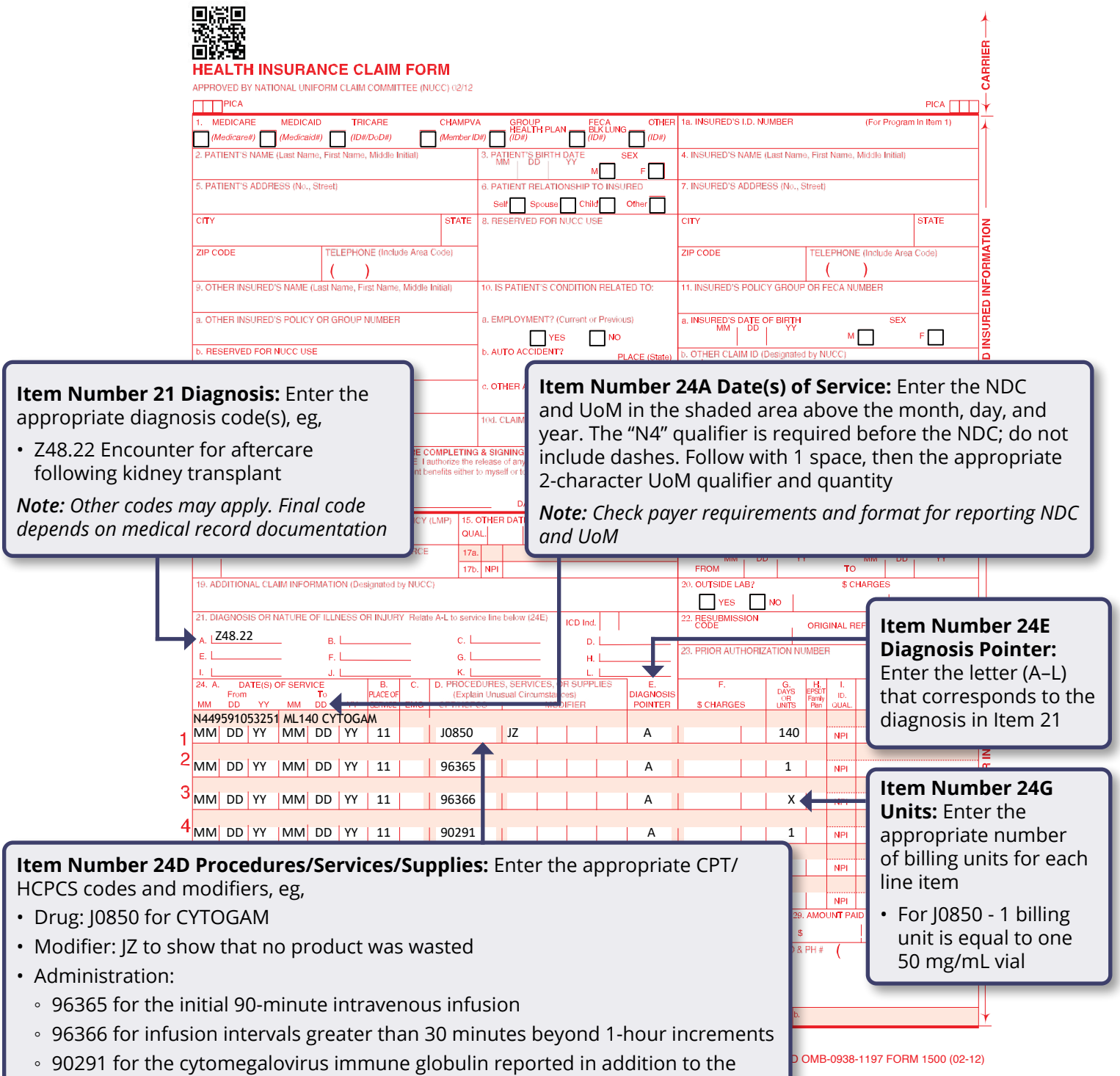
- Z48.22 Encounter for aftercare following kidney transplant

Note: *Other codes may apply. Final code depends on medical record documentation*

Sample Claim Form: CMS-1500 Independent Infusion Center

This sample claim form is intended as a reference for the billing and coding of CYTOGAM. This form is not intended to be directive, and the use of the recommended codes does not guarantee reimbursement. Independent infusion centers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice, patients, and services rendered.

The following is an example of a 70 kg patient receiving a 7,000 mg intravenous infusion of CYTOGAM within 4 weeks post kidney transplant.



Item Number 21 Diagnosis: Enter the appropriate diagnosis code(s), eg,

- Z48.22 Encounter for aftercare following kidney transplant

Note: *Other codes may apply. Final code depends on medical record documentation*

Item Number 24A Date(s) of Service: Enter the NDC and UoM in the shaded area above the month, day, and year. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UoM qualifier and quantity

Note: *Check payer requirements and format for reporting NDC and UoM*

Item Number 24E Diagnosis Pointer: Enter the letter (A–L) that corresponds to the diagnosis in Item 21

Item Number 24G Units: Enter the appropriate number of billing units for each line item

- For J0850 - 1 billing unit is equal to one 50 mg/mL vial

Item Number 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, eg,

- Drug: J0850 for CYTOGAM
- Modifier: JZ to show that no product was wasted
- Administration:
  - 96365 for the initial 90-minute intravenous infusion
  - 96366 for infusion intervals greater than 30 minutes beyond 1-hour increments
  - 90291 for the cytomegalovirus immune globulin reported in addition to the code for CYTOGAM

Best practices for submitting clean claims

The following may be considered to assist with submitting claims for CYTOGAM completely and accurately, which is important for timely claims processing, appropriate payment, and preventing denied claims.

Provide the patient's name, address, and insurance identification number, and review each for accuracy

Include the HCP's name, National Provider Identifier (NPI), and payer-specific provider ID (if applicable)

Check to ensure that ICD-10-CM diagnosis codes, CPT procedure codes, and modifiers (if applicable) are valid and consistent with information included in the patient's medical record

Review the CYTOGAM product-specific information (eg, HCPCS code, NDC 11-digit format, correct number of billing units)

References

1. Centers for Medicare & Medicaid Services. January 2026 alpha-numeric HCPCS file. Accessed December 20, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
2. Food and Drug Administration. Format of the National Drug Code. Accessed December 20, 2025. https://www.fda.gov/media/173715/download
3. Cytogam. Prescribing information. Kamada Inc; 2022.
4. American Medical Association. CPT 2026 Professional Edition. AMA; 2025. All rights reserved. CPT® is a registered trademark of the American Medical Association.
5. Noridian Healthcare Solutions. Revenue codes. Accessed December 20, 2025. https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes
6. Centers for Medicare & Medicaid Services. 2026 ICD-10-CM code tables, tabular, and index. Accessed December 20, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes
7. Centers for Medicare & Medicaid Services. FY 2026 ICD-10-CM Coding Guidelines. Accessed December 20, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes
8. Centers for Medicare & Medicaid Services. MS-DRG Classifications and Software. V43 Definitions Manual Table of Contents. Accessed December 20, 2025. https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software

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Kamada Inc., 221 River St, Hoboken, NJ 07030
Tel. 1-833-779-2614

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