Medical Policy:

Cytogam® (cytomegalovirus immune globulin, human) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.139	March 26, 2025	

Definition

Cytogam is an injectable product that contains antibodies directed specificial cytomegalovirus (CMV), which is generally present in persons who have been exposed to the virus. While CMV in adults is typically benign in healthy people, it is a significant cause of morbidity and mortality in people who are immunosuppressed due to organ transplantation or AIDS. Cytomegalovirus Immune Globulin IV is currently approved by the Food and Drug Administration (FDA) for use in attentuation of CMV disease in renal transplant patients. It also has been shown to be beneficial in prevention and CMV disease in patients who have received an orthotopic liver transplant. There is also evidence for use of CMV organ transplants (such as heart and lung) and in bone marrow transplants.

Length of Authorization

Coverage will be provided for 12 months.

Guideline

I. Initial Approval Criteria

Cytogam *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **<u>Cytomegalovirus infection, Prophylaxis – Transplantation of any of the following;</u>**
    A. Kidney
    B. Lung
    C. Liver
    D. Pancreas
    E. Heart

Limitations/Exclusions

Cytogam is not considered medically necessary for when any of the following selection criteria is met:

1. Persons with selective IgA deficiency with antibodies to IgA **AND** a history of anaphylactic reactions to human immune globulin preparations.
2. History of prior severe reaction associated with the administration of Cytogam or any other human immunoglobulin preparations.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA.

Dosage/Administration

Indication	Dose
Cytomegalovirus infection; Prophylaxis - Transplant of kidney	150 mg/kg IV for 1 dose within 72 hours of transplant then 100 mg/kg on weeks 2,4,6, and 8 post transplant and 50 mg/kg on weeks 12 and 16 post transplant
Cytomegalovirus infection; Prophylaxis - Transplant of Lung	150 mg/kg IV within 72 hours of transplant and on weeks 2,4,6, and 8 post transplant and 100 mg/kg on weeks 12 and 16 post transplant
Cytomegalovirus infection; Prophylaxis - Transplant of Liver	150 mg/kg IV within 72 hours of transplant and on weeks 2,4,6, and 8 post transplant and 100 mg/kg on weeks 12 and 16 post transplant
Cytomegalovirus infection; Prophylaxis - Transplant of Pancreas	150 mg/kg IV within 72 hours of transplant and on weeks 2,4,6, and 8 post transplant and 100 mg/kg on weeks 12 and 16 post transplant
Cytomegalovirus infection; Prophylaxis - Transplant of Heart	150 mg/kg IV within 72 hours of transplant and on weeks 2,4,6, and 8 post transplant and 100 mg/kg on weeks 12 and 16 post transplant

Applicable Procedure Codes

Code	Description
J0850	Injection, cytomegalovirus immune globulin intravenous (human), 1 billable unit = per vial
90291	Cytomegalovirus immune globulin (CMV-IgIV), human, for intravenous use

Applicable NDCs

Code	Description
44206-0532-xx	Cytogam 50mg/mL single use vial

ICD-10 Diagnoses

Code	Description
B25.0	Cytomegaloviral pneumonitis
B25.1	Cytomegaloviral hepatitis

B25.2	Cytomegaloviral pancreatitis
P35.1	Congenital cytomegalovirus infection
T86.1	Complications of kidney transplant
T86.10	Unspecified complication of kidney transplant
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant
T86.2	Complications of heart transplant
T86.20	Unspecified complication of heart transplant
T86.21	Heart transplant rejection
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.29	Other complications of heart transplant
T86.298	Other complications of heart transplant
T86.30	Unspecified complication of heart-lung transplant
T86.31	Heart-lung transplant rejection
T86.32	Heart-lung transplant failure
T86.33	Heart-lung transplant infection
T86.39	Other complications of heart-lung transplant
T86.4	Complications of liver transplant
T86.40	Unspecified complication of liver transplant
T86.41	Liver transplant rejection
T86.42	Liver transplant failure
T86.43	Liver transplant infection
T86.49	Other complications of liver transplant
T86.81	Complications of lung transplant
T86.810	Lung transplant rejection
T86.811	Lung transplant failure
T86.812	Lung transplant infection
T86.818	Other complications of lung transplant
T86.819	Unspecified complication of lung transplant
T86.89	Complications of other transplanted tissue
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.892	Other transplanted tissue infection
T86.898	Other complications of other transplanted tissue
T86.899	Unspecified complication of other transplanted tissue
T86.9	Complication of unspecified transplanted organ and tissue
T86.90	Unsp complication of unspecified transplanted organ and tissue
T86.91	Unspecified transplanted organ and tissue rejection
T86.92	Unspecified transplanted organ and tissue failure
T86.93	Unspecified transplanted organ and tissue failure
T86.99	Other complications of unspecified transplanted organ and tissue
Z29.1	Encounter for prophylactic immunotherapy
Z29.8	Encounter for other specified prophylactic measures

Z29.9	Encounter for prophylactic measures, unspecified
Z48.2	Encounter for aftercare following organ transplant
Z48.21	Encounter for aftercare following heart transplant
Z48.22	Encounter for aftercare following kidney transplant
Z48.23	Encounter for aftercare following liver transplant
Z48.24	Encounter for aftercare following lung transplant
Z48.28	Encounter for aftercare following multiple organ transplant
Z48.280	Encounter for aftercare following heart-lung transplant
Z48.288	Encounter for aftercare following multiple organ transplant
Z94.0	Kidney transplant status
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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/26/2025	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	3/20/2024	Annual Review: added 90291, updated NDC
EmblemHealth & ConnectiCare	7/18/2023	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	4/11/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/15/2019	Annual review

References

1. Cytogam intravenous infusion [prescribing information]. Hoboken, NJ: Kamada; September 2022.