



UTILIZATION MANAGEMENT MEDICAL POLICY

- POLICY:** Immune Globulin – Cytogam Management Review Medical Policy
- Cytogam[®] (human cytomegalovirus immune globulin intravenous infusion – Saol Therapeutics)

REVIEW DATE: 12/08/2021

OVERVIEW

Cytogam, a human cytomegalovirus (CMV) immune globulin intravenous (IGIV), is indicated for the **prophylaxis of CMV disease** associated with transplantation of kidney, lung, liver, pancreas and heart.¹

Other Uses With Supportive Evidence

Maternal transmission of CMV to the fetus may occur at any time during gestation, leading to congenital CMV.² A study of 304 pregnant women with a primary CMV infection were offered CMV IGIV. In the therapy group, 157 women were treated with CMV IGIV low dose (100 mg/kg/infusion given once every month) or high dose (200 mg/kg/infusion given once every 2 weeks for up to 3 doses if needed). The trial demonstrated that 56% of patients without CMV IGIV vs. 30% of patients receiving CMV IGIV developed congenital CMV infection.

Dosing Information

The maximum recommended dosage for prophylaxis of CMV disease associated with transplantation of kidney, lung, liver, pancreas, and heart is 150 mg/kg per intravenous infusion with a total of 7 infusions.¹ The first infusion should be within 72 hours of transplant followed by infusions at Week 2, 4, 6, 8, 12, and 16 post-transplant.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Cytogam. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cytogam as well as the monitoring required for adverse events and long-term efficacy, approval requires Cytogam to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cytogam is recommended in those who meet one of the following criteria:

FDA-Approved Indication

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- 1. Prophylaxis of Cytomegalovirus Associated with Solid Organ Transplant.** Approve for 4 months if the medication is prescribed by or in consultation with a physician affiliated with a transplant center, hematologist, or an infectious disease physician.

Dosing. Approve up to 150 mg/kg given by intravenous infusion no more frequently than every 2 weeks.

Other Uses with Supportive Evidence

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- 2. Cytomegalovirus Associated with Pregnancy.** Approve for 6 months if the medication is prescribed by or in consultation with an infectious disease physician or an obstetrician-gynecologist.

Dosing. Approve the following dosing regimens (A or B):

- A) Up to 100 mg/kg given by intravenous infusion no more frequently than every month; OR
- B) Up to 200 mg/kg given by intravenous infusion and the number of doses given does not exceed 3 doses total.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cytogam is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cytogam intravenous infusion [prescribing information]. Roswell, GA: Saol Therapeutics; October 2020.
2. Swanson E, Schleiss M. Congenital cytomegalovirus infection: New prospects for prevention and therapy. *Pediatric Clinics of North America*. 2013;60:335-349.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Prophylaxis of Cytomegalovirus Associated with Solid Organ Transplant. Dosing was clarified to state that the dose is given by intravenous infusion. Cytomegalovirus Associated with Pregnancy. Dosing was clarified to state that the dose is given by intravenous infusion.	12/02/2020
Annual Revision	No criteria changes.	12/08/2021