VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Immune Globulin – Cytogam Utilization Management Medical Policy
- Cytogam® (human cytomegalovirus immune globulin intravenous infusion – Kamada)

REVIEW DATE: 01/17/2024

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.

CMV can cause complications in immunocompromised patients, including patients who have received a stem cell transplant or who have human immunodeficiency virus.[3,4] Small analyses have shown that CMV hyperimmune globulin, given as salvage or rescue therapy (after standard antiviral drug therapy), may be beneficial.[4,5] Additionally, CMV immune globulin has been designated as an orphan drug by the FDA for use in conjunction with ganciclovir for the treatment of CMV pneumonitis.[6] Higher doses of 400 mg/kg intravenously have been given off-label for the treatment of CMV pneumonitis.

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.

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3. **Cytomegalovirus, Treatment.** Approve for 6 months if the patient meets the following (A and B):
   A) Patient meets one of the following (i or ii):
      i. Patient is being treated for cytomegalovirus pneumonitis; OR
      ii. Patient meets both of the following (a and b):
      Note: For cytomegalovirus retinitis, use of the following medications given by intravitreal or by an ocular implant would satisfy the requirement.
         a) Patient has tried or is unable to use one of the following systemic therapies:
            (1) Ganciclovir; OR
            (2) Valganciclovir; AND
         b) Patient has tried or is unable to use foscarnet (Foscavir intravenous infusion); AND
   B) Cytogam has been prescribed by or in consultation with an infectious disease specialist, an ophthalmologist, a physician associated with a transplant center, an oncologist, or a hematologist.

   Dosing. Approve the following dosing regimens (A or B):
   A) Up to 400 mg/kg given daily by intravenous infusion; OR
   B) The dosing regimen is based on a transplant center's protocol.

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. *Pediatr Clin North Am.* 2013;60:335-349.
3. Zhang J, Kamoi K, Zong Y, et al. Cytomegalovirus anterior uveitis: Clinical manifestations, diagnosis, treatment, and immunological mechanisms. *Viruses.* 2023;15(1):185.
4. Panesso M, Luz Uria M, Renedo B, et al. CMV hyperimmune globulin as salvage therapy for recurrent or refractory CMV infection in children undergoing hematopoietic stem cell transplantation. *Front Pediatr.* 2023;11:1197828.
5. Belaiche S, Delage J, Alain S, et al. Cytotect® CP as salvage therapy in patients with CMV infection following allogeneic hematopoietic cell transplantation: a multicenter retrospective study. *Bone Marrow Tranplant.* 2018;53(10):1328-1335.
6. Clinical Pharmacology [database online]. Elsevier 2024. Available at: Clinical Pharmacology Home (clinicalkey.com). Accessed on January 4, 2023. Search term: Cytogam.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/08/2021
Annual Revision	No criteria changes.	12/14/2022
Annual Revision	**Cytomegalovirus, Treatment**. This new condition of approval and criteria was added to the policy	01/17/2024