

**Cytogam (Cytomegalovirus Immune Globulin Intravenous [Human])
 Effective 01/01/2024**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Cytogam (CMV-IGIV), is an immunoglobulin G (IgG) containing a standardized amount of antibody to Cytomegalovirus (CMV). Cytogam is FDA indicated for prophylaxis of cytomegalovirus (CMV) disease associated with transplantation of kidney, lung, liver, pancreas, and heart; concomitant use with ganciclovir should be considered in organ transplants (other than kidney) from CMV seropositive donors to CMV seronegative recipients

Compendial Uses

- Treatment of CMV pneumonitis in bone marrow transplant recipients
- Treatment or prevention of congenital CMV infection

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Authorization may be granted when the following indication specific criteria is met:

1. CMV prophylaxis in solid organ transplant recipients

Authorization may be granted for members with a diagnosis of CMV prophylaxis who are solid organ transplant recipients (e.g., heart, liver, lung) and are prescribed Cytogam for the prevention of CMV disease.

2. CMV pneumonitis in transplant recipients

Authorization may be granted for members with a diagnosis of CMV pneumonitis who are transplant recipient and are prescribed Cytogam in combination with an antiretroviral medication for the treatment of CMV pneumonitis.

3. Congenital CMV infection

Authorization may be granted to members who are prescribed Cytogam for the treatment of CMV infection during pregnancy.

Continuation of Therapy

Reauthorization may be granted for members, including those who are new to the plan, when ALL initial criteria are met.

Limitations

1. Approvals for CMV prophylaxis and pneumonitis will be granted for 12 months.
2. Approvals for congenital CMV infection will be granted for one dose.
3. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

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6. Reed EC, Bowden RA, Dandliker PS, et al. Treatment of cytomegalovirus pneumonia with ganciclovir and intravenous cytomegalovirus immunoglobulin in patients with bone marrow transplants. *Ann Intern Med.* 1988; 109:783.
7. Schmidt GM, Kovacs A, Zaia JA, et al. Ganciclovir/immunoglobulin combination therapy for the treatment of human cytomegalovirus-associated interstitial pneumonia in bone marrow allograft recipients. *Transplantation.* 1988; 46:905.
8. Kotton CN, Kumar D, Caliendo AM, et al. The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation. *Transplantation* 2018; 102:900
9. Bonaros N, Mayer B, Schachner T, Laufer G, Kocher A. CMV-hyperimmune globulin for preventing cytomegalovirus infection and disease in solid organ transplant recipients: a meta-analysis. *Clin Transplant.* 2008;22(1):89-97.
10. Husain S, Sole A, Alexander BD, et al. The 2015 International Society for Heart and Lung Transplantation Guidelines for the management of fungal infections in mechanical circulatory support and cardiothoracic organ transplant recipients: Executive summary. *J Heart Lung Transplant* 2016; 35:261
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13. D'Alessandro AM, Pirsch JD, Stratta RJ, et al. Successful treatment of severe cytomegalovirus infections with ganciclovir and CMV hyperimmune globulin in liver transplant recipients. *Transplant Proc.* 1989; 21:3560-1.
14. Lazzarotto T, Guerra B, Gabrielli L, et al. Update on the prevention, diagnosis and management of cytomegalovirus infection during pregnancy. *Clin Microbiol Infect* 2011; 17:1285.



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16. Baker AW, Maziarz EK, Arnold CJ, et al. Invasive Fungal Infection After Lung Transplantation: Epidemiology in the Setting of Antifungal Prophylaxis. *Clin Infect Dis* 2020; 70:30

Review History

02/27/17 – Reviewed

10/01/17 – Effective

02/26/18 – Reviewed

02/20/19 – Reviewed

07/21/2021- Reviewed at P&T; no clinical changes, overview reworded.

12/13/2023 – Reviewed and Updated for Dec P&T; updated benefit to Medical benefit. No clinical changes.

Effective 1/1/2024

