

Cytogam (Cytomegalovirus Immune Globulin Intravenous [Human])
Effective 02/20/19

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Cytogam is indicated for the prophylaxis of cytomegalovirus (CMV) 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 Cytogam should be considered in combination with ganciclovir.

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:

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.



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.

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 AllWays Health Partners, 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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2. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed December 17, 2015.
3. Bratanow NC, Ash RC, Turner PA, et al. Successful treatment of serious cytomegalovirus disease with 9 (1,3-dihydroxy-2-propoxymethyl)-guanine and intravenous immunoglobulin in bone marrow transplant patients. *Exp Hematol*. 1987;15:541.
4. Ljungman P, Englehard D, Link H, et al. Treatment of interstitial pneumonitis due to cytomegalovirus with ganciclovir and intravenous immune globulin: Experience of European Bone Marrow Transplant Group. *Clin Infect Dis*. 1992; 14:831.
5. Barber L, Egan JJ, Lomax J, et al. A prospective study of a quantitative PCR ELISA assay for the diagnosis of CMV pneumonia in lung and heart-transplant recipients. *J Heart Lung Transplant* 2000; 19:771.
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 for the Transplantation Society International CMV Consensus Group. International consensus guidelines on the management of cytomegalovirus in solid organ transplantation. *Transplantation*. 2010;89(7):779-795.
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.
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12. Lopez G, Garcia F, Laporta R, et al. Cytomegalovirus immunoglobulin for prophylaxis and treatment of cytomegalovirus infection in the (Val)Ganciclovir Era: A Single-Center Experience. *Ann. Transplant.* 2015; 20:661-666.
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.
15. Snyder LD, Finlen-Copeland CA, Turbyfill WJ, et al. Cytomegalovirus pneumonitis is a risk for bronchiolitis obliterans syndrome in lung transplantation. *Am J Respir Crit Care Med* 2010; 181:1391.

Review History

02/27/17 – Reviewed
10/01/17 – Effective
02/26/18 – Reviewed
02/20/19 – Reviewed

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