

PHARMACY POLICY STATEMENT North Carolina Marketplace

DRUG NAME	Cytogam (cytomegalovirus immune globulin)
BILLING CODE	J0850
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Cytogam is an immunoglobulin G (IgG) containing a standardized amount of antibody to Cytomegalovirus (CMV) initially approved by the FDA in 1987. The globulin contains a relatively high concentration of antibodies directed against Cytomegalovirus (CMV). In the case of persons who may be exposed to CMV, Cytogam can raise the relevant antibodies to levels sufficient to attenuate or reduce the incidence of serious CMV disease. Cytomegalovirus Immune Globulin Intravenous (Human) is indicated for the prophylaxis of cytomegalovirus 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 CMV-IGIV should be considered in combination with ganciclovir and valganciclovir. Because efficacy data are limited, many experts do not favor the addition of CMV immunoglobulin to treatment regimens; this approach is no longer recommended in the 2013 international consensus guidelines.

Cytogam (cytomegalovirus immune globulin) will be considered for coverage when the following criteria are met:

CMV Prophylaxis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an infectious disease specialist or transplant specialist; AND
3. Member is the recipient of a solid organ transplant (i.e. kidney, lung, liver, pancreas, heart transplant);
4. Member or donor must be CMV-seropositive;
5. Prescriber attests Cytogam will be used with other antiviral therapy (i.e. ganciclovir, valganciclovir); AND
6. **Dosage allowed/Quantity limit:** The maximum recommended total dosage per infusion is 150 mg Ig/kg, administered according to the following schedule:

Type of transplant

	Kidney	Liver, Pancreas, Lung, Heart
Within 72 hours of transplant:	150 mg/kg	150 mg/kg
2 weeks post-transplant:	100 mg/kg	150 mg/kg
4 weeks post-transplant:	100 mg/kg	150 mg/kg
6 weeks post-transplant:	100 mg/kg	150 mg/kg
8 weeks post-transplant:	100 mg/kg	150 mg/kg
12 weeks post-transplant:	50 mg/kg	100 mg/kg
16 weeks post-transplant:	50 mg/kg	100 mg/kg



If all the above requirements are met, the medication will be approved for 16 weeks.

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource considers Cytogam (cytomegalovirus immune globulin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
02/15/2022	New policy for Cytogam created.

References:

1. Cytogam [prescribing information]. Roswell, GA: Saol Therapeutics, Inc; August 2020.
2. Alexander BT, Hladnik LM, Augustin KM, et al, "Use of Cytomegalovirus Intravenous Immune Globulin for the Adjunctive Treatment of Cytomegalovirus in Hematopoietic Stem Cell Transplant Recipients," *Pharmacotherapy*, 2010, 30(6):554-61.
3. Snyderman DR, Werner BG, Heinze-Lacey BH, et al. Use of cytomegalovirus immune globulin to prevent cytomegalovirus disease in renal transplant recipients. *N Engl J Med* 1987;317:1049-1054.
4. Snyderman DR, Werner BG, Dougherty NN, et al. Cytomegalovirus Immune Globulin prophylaxis in liver transplantation. A randomized, double-blind, placebo-controlled trial. *Ann Int Med* 1993;119:984-991.
5. Falagas ME, Snyderman DR, Ruthazer R, et al. Cytomegalovirus Immune Globulin (CMVIG) prophylaxis is associated with increased survival after orthotopic liver transplantation. *Clin Transplant* 1997;11:432-437.
6. Snyderman DR, Werner BG, Tilney NL, et al. A final analysis of primary cytomegalovirus disease prevention in renal transplant recipients with a cytomegalovirus immune globulin: Comparison of randomized and open-label trials. *Transplant Proc* 1991;23:1357-1360.

Effective date: 01/01/2023

Revised date: 02/15/2022