MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
03/01/2013	07/13/2016	07/14/2015

Policy Name	Policy Number
Cytomegalovirus Immune Globulin Intravenous (Cytogam)	SRx-0039

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Cytomegalovirus Immune Globulin Intravenous (Cytogam)

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the **Cytomegalovirus Immune Globulin Intravenous (Cytogam)** pre-authorization (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

IVIG- Intravenous Immune Globulin
CMV- Cytomegalovirus

D. POLICY

CareSource will approve the use of CMV-IVIG **(Cytogam)** and consider its use as medically necessary when the following criteria have been met for:

I. Cytomegalovirus infection prophylaxis associated with organ transplantation of the kidney, lung, liver, pancreas and heart

Cytomegalovirus Infection Prophylaxis

Cytomegalovirus Immune Globulin Intravenous (Human) is indicated for the prophylaxis of cytomegalovirus infection associated with transplantation of kidney, lung, liver, pancreas and heart. Cytogam will be considered medically necessary if the patient meets all of the following criteria:

A. Cytomegalovirus seronegative recipient of a cytomegalovirus seropositive kidney, lung, liver, pancreas or heart
B. Documentation of a positive CMV PCR or CMV antigenemia assay
C. Cytogam will be used in combination with an antiviral except for kidney transplant patients

Note: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of infection and will need to be supplied with prior authorization request. These medical records many include, but are not limited to, test reports, chart notes from provider's office or hospital admission notes.

Note: During administration, the patient's vital signs should be monitored continuously and careful observation made for any symptoms throughout the infusion. Epinephrine should be available for the treatment of an acute anaphylactic reaction.

Note: Patient is required to have completed the trial listed in the above criteria unless the patient is unable to tolerate or has a contraindication. Documentation such as chart notes or pharmacy claims may be requested.

All other uses of CMV-IVIG (Cytogam) are considered experimental/investigational and therefore will follow the CareSource Policy for Off-Label and Excluded benefits.

Refer to the product package insert for dosing, administration and safety guidelines.

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS J0850
CPT

AUTHORIZATION PERIOD

Approved initial authorizations are valid for 16 weeks (4 months). Continued treatment may be considered if the member shows a need for continued prophylaxis. **ALL** authorizations are subject to continued eligibility.

PLACE OF SERVICE

Outpatient, Home per home health
**Preferred place of service is in the home.
Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any

required monitoring or additional services that may coincide with the delivery of the specific medication.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued: 01/18/2013
Date Reviewed: 01/18/2013, 05/13/2014, 07/14/2015
Date Revised: 05/13/2014, 7/14/2015

G. REFERENCES

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2. Facts and Comparison. http://online.factsandcomparisons.com/index.aspx Preiksaitis JK, Brennan DC, Fishman J, et al. Canadian society of transplantation consensus workshop on cytomegalovirus management in solid organ transplantation final report. *Am J Transplant*. 2005 Feb;5(2):218-27.
3. George MJ, Snydman DR, Werner BG, et al. Use of ganciclovir plus cytomegalovirus immune globulin to treat CMV pneumonia in orthotopic liver transplant recipients. The Boston Center for Liver Transplantation CMVIG-Study Group. *Transplant Proc*. 1993 Oct;25(5 Suppl 4):22-4.
4. Kotton CN, Kumar D, Caliendo AM, Asberg A, Chou S, Danziger-Isakov L, Humar A, Transplantation Society International CMV Consensus Group; Transplantation. 2013;96(4):333. American Society of Transplantation – 2013
5. Kwon, S., Jung, B. K., Ko, S.-Y., Lee, C. K., & Cho, Y. (2015). Comparison of Quantitation of Cytomegalovirus DNA by Real-Time PCR in Whole Blood with the Cytomegalovirus Antigenemia Assay. *Annals of Laboratory Medicine*,*35*(1), 99–104. doi:10.3343/alm.2015.35.1.99
6. http://emedicine.medscape.com/article/215702-treatment. June 25,2015

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.