MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
03/01/2013	07/13/2017	05/03/2016

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

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to Medical health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, 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 federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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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

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

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

II. Cytomegalovirus Infection Prophylaxis
   A. 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:
      1. Cytomegalovirus seronegative recipient of a cytomegalovirus seropositive kidney, lung, liver, pancreas or heart
      2. Documentation of a positive CMV PCR or CMV antigenemia assay
      3. 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.

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, 05/03/2016
Date Revised: 05/13/2014, 7/14/2015

G. REFERENCES

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