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 may 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

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