SPECIALTY GUIDELINE MANAGEMENT

Cytogam (Cytomegalovirus Immune Globulin Intravenous [Human])

POLICY

A. INDICATIONS
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.

B. EXCLUSIONS
• History of a prior severe reaction associated with the administration of Cytogam or any other human immunoglobulin preparations
• Persons with selective IgA deficiency with antibodies to IgA and a history of anaphylactic reactions to human immune globulin preparations

C. CRITERIA FOR APPROVAL
1. CMV prophylaxis in solid organ transplant recipients
Authorization of 12 months may be granted to members who are solid organ transplant recipients (e.g., heart, liver, lung) and are prescribed Cytogam for the prevention of CMV disease.

2. CMV pneumonitis in bone marrow transplant recipients
Authorization of 12 months may be granted to members who are bone marrow transplant recipients and are prescribed Cytogam in combination with an antiretroviral medication for the treatment of CMV pneumonitis.

3. Congenital CMV infection
Authorization of one dose may be granted to members who are prescribed Cytogam for the treatment of CMV infection during pregnancy.

D. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Cytogam SGM P2015

CVS Caremark is an independent company that provides pharmacy benefit management services to CareFirst and BlueChoice members.

CareFirst BlueCross BlueShield is the shared business name of CareFirst of Maryland, Inc. and Group Hospitalization and Medical Services, Inc. CareFirst BlueCross BlueShield and CareFirst BlueChoice, Inc. are both independent licensees of the Blue Cross and Blue Shield Association. The Blue Cross and Blue Shield Names and Symbols are registered trademarks of the Blue Cross and Blue Shield Association. ® Registered trademark of CareFirst of Maryland, Inc.
REFERENCES