Cytogam (Cytomegalovirus Immune Globulin Intravenous [Human])
Prior Authorization Criteria
Drug Protocol Management
MassHealth/Commercial/Exchange

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. 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 transplant recipients**
   Authorization of 12 months may be granted to members who are 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.

C. CONTINUATION OF THERAPY

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

D. DOSAGE AND ADMINISTRATION

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

References

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Review History

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