# Cytogam (cytomegalovirus immune globulin)
# Policy Number: C9970-A

**CRITERIA EFFECTIVE DATES:**

| ORIGINAL EFFECTIVE DATE | LAST REVIEWED DATE | NEXT REVIEW DUE BY OR BEFORE |
|---|---|---|
| 12/1/2016 | 11/18/2020 | 1/26/2022 |
| **J CODE** | **TYPE OF CRITERIA** | **LAST P&T APPROVAL/VERSION** |
| 90291-cytomegalovirus immune globulin intravenous human J0850-injection, cytomegalovirus immune globulin intravenous (human), per vial | RxPA | Q1 2021 20210127C9970-A |

**PRODUCTS AFFECTED:**
Cytogam (cytomegalovirus immune globulin)

**DRUG CLASS:**
Immune Serums

**ROUTE OF ADMINISTRATION:**
Intravenous

**PLACE OF SERVICE:**
Specialty Pharmacy or Buy and Bill
The recommendation is that medications in this policy will be for medical benefit coverage and the product is administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the therapy/member meets the Site of Care exceptions. (See appendix for excerpt from Specialty Medication Administration Site of Care Policy)

**AVAILABLE DOSAGE FORMS**:
Cytogam INJ 50MG/ML

**FDA-APPROVED USES:**
Cytomegalovirus Immune Globulin Intravenous (Human) is indicated for:

- the prophylaxis of cytomegalovirus 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 CMV-IGIV should be considered in combination with ganciclovir

**COMPENDIAL APPROVED OFF-LABELED USES:**
Cytomegalovirus (CMV) pneumonitis in solid organ transplant (adjunctive therapy); Cytomegalovirus (CMV) pneumonitis in hematopoietic stem cell transplant (HSCT) (adjunctive therapy)

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:**
prophylaxis of cytomegalovirus (CMV) disease post organ transplantation, including kidney, liver, lung, pancreas, and heart transplantation, Cytomegalovirus (CMV) pneumonitis in solid organ transplant (adjunctive therapy); Cytomegalovirus (CMV) pneumonitis in hematopoietic stem cell transplant (HSCT) (adjunctive therapy)

**REQUIRED MEDICAL INFORMATION:**

A. CYTOMEGALOVIRUS PROPHYLAXIS POST SOLID ORGAN TRANSPLANT:
1. Documentation member has a history of a kidney, lung, liver, pancreas, heart, and kidney-pancreas transplant
   AND
2. Organ donor or recipient is CMV seropositive
   AND
3. Prescriber attests that CMV immunoglobulin will be provided in addition to antiviral therapies (valganciclivir, ganciclovir, foscarnet, etc.)

B. CYTOMEGALOVIRUS (CMV) PNEUMONITIS:
1. Documentation diagnosis of cytomegalovirus pneumonitis
   AND
2. Documentation that Cytomegalovirus Immune Globulin (CMV-IVIG) will be used on combination with antiviral therapy

**DURATION OF APPROVAL:**
CYTOMEGALOVIRUS PROPHYLAXIS POST SOLID ORGAN TRANSPLANT: Initial authorization: 16 weeks. Reauthorization beyond 16 weeks is not permitted. Members must meet the initial approval criteria.
CYTOMEGALOVIRUS (CMV) PNEUMONITIS: Initial authorization: 1 month, Reauthorization beyond 1 month is not permitted. Members must meet the initial approval criteria.

**QUANTITY:**
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

**PRESCRIBER REQUIREMENTS:**
Prescribed by or in consultation with an immunologist, nephrologist, pulmonologist, hepatologist, gastroenterologist, cardiologist, or transplant specialist

**AGE RESTRICTIONS:**
18 years of age and older

**CONTINUATION OF THERAPY:**
NA Must meet initial criteria

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**
All other uses of CMV-IVIG (Cytogam) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Cytogam (cytomegalovirus immune globulin intravenous) is contraindicated in members with a history of prior severe reaction associated with the administration of any human immunoglobulin preparations and members with selective IgA deficiency with antibodies to IgA and a history of anaphylactic reactions to human immune globulin preparations.

**OTHER SPECIAL CONSIDERATIONS:**
None

**BACKGROUND:**
**For primary cytomegalovirus (CMV) disease prophylaxis after organ transplantation, including kidney, lung, liver, pancreas, and heart transplantation.**
In CMV seronegative recipients of a renal allograft from a CMV seropositive donor. 150 mg/kg by IV infusion administered within 72 hours posttransplant. Subsequent single IV doses of 100 mg/kg are administered at 2, 4, 6, and 8 weeks posttransplant. Then, the dosage is decreased to 50 mg/kg IV as a single dose during weeks 12 and 16 posttransplant.
In CMV seronegative recipients of a heart, liver, lung, or pancreas allograft from a CMV seropositive donor. 150 mg/kg IV given within 72 hours of transplant. Subsequent single doses of 150 mg/kg IV are given 2, 4, 6, and 8 weeks following transplantation. Then, the dosage is decreased to 100 mg/kg IV as a single dose during weeks 12 and 16 post-transplant. The manufacturer recommends consideration of adding ganciclovir in these patients. The efficacy of CMV-IVIG in preventing CMV and related infections was studied in a trial of patients receiving CMV-positive liver transplants.
CMV-IVIG reduced the incidence of severe CMV-associated disease, including CMV pneumonia, multiorgan CMV disease, and invasive fungal disease in all serologic groups, regardless of recipient/donor CMV serologic status, except for the CMV-seropositive donor/CMV-seronegative recipient group.

**Use NOT supported by evidence:**
**In CMV seronegative recipients of a bone marrow allograft from a CMV seropositive donor**. In 1 study, bone marrow transplant patients were randomized to receive CMV-IVIG 200 mg/kg IV on days 8 and 6 pretransplant, on the day after marrow infusion, and on days 7, 14, 21, 28, 42, 56, and 70 for a total of 10 doses or no CMV-IVIG as primary prophylaxis of CMV infection. Although CMV viremia and excretion were less in the active drug group, there was no difference between groups with regard to clinical CMV disease.

**APPENDIX:**
None
Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:

1. The member is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The member exhibits physical or cognitive impairment and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the patient's first dose of the medication or it is being re-initiated after at least 12 months*
5. The member has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at an non-hospital facility based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

*Note: a hospital outpatient setting or a hospital-affiliated infusion suite is expected to have*

*immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary*

***Documentation Requirements:***
*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

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**REFERENCES:**


1. Cytogam (cytomegalovirus immune globulin intravenous [human]) [prescribing information]. Kankakee, IL: CSL Behring LLC; November 2017.
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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.
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6. Alexander BT, Hladnik LM, Augustin KM, et al, “Use of Cytomegalovirus Intravenous Immune Globulin for the Adjunctive Treatment of Cytomegalovirus in Hematopoietic Stem Cell Transplant Recipients,” Pharmacotherapy, 2010, 30(6):554-61