Original Effective Date: 12/01/2016
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C9970-A

Cytogam (cytomegalovirus immune globulin)

PRODUCTS AFFECTED

Cytogam (cytomegalovirus immune globulin)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

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.

DIAGNOSIS:
Cytomegalovirus prophylaxis post solid organ transplant, Cytomegalovirus pneumonitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CYTOMEGALOVIRUS PROPHYLAXIS POST SOLID ORGAN TRANSPLANT:
   1. Documentation member has a history of a kidney, lung, liver, pancreas, heart, or kidney-pancreas transplant
      AND

2. Organ donor or recipient is CMV seropositive
   AND
3. Prescriber attests that CMV immune globulin will be provided in addition to antiviral therapies (valganciclovir, ganciclovir, foscarnet, etc.)

B. CYTOMEGALOVIRUS (CMV) PNEUMONITIS:
1. Documented diagnosis of cytomegalovirus pneumonitis
   AND
2. Documentation that Cytomegalovirus immune globulin will be provided in addition to antiviral therapies (i.e., valganciclovir, ganciclovir)

CONTINUATION OF THERAPY:
N/A Must meet initial criteria

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

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an immunologist, nephrologist, pulmonologist, hepatologist, gastroenterologist, cardiologist, infectious disease or transplant specialist. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

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

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Immune Serums

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)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

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.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Cytogam (cytomegalovirus immune globulin intravenous) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy.
Contraindications to Cytogam (cytomegalovirus immune globulin intravenous) include: individuals with a history of prior severe reaction associated with the administration of this or other human immunoglobulin preparations and persons with selective IgA deficiency with antibodies to IgA and a history of anaphylactic reactions to human immune globulin preparations.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device*

code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
J0850	Injection, cytomegalovirus immune globulin intravenous (human), per vial
90291	Cytomegalovirus immune globulin (CMV-IgIV), human, for intravenous use

AVAILABLE DOSAGE FORMS:
Cytogam INJ 50MG/ML single-dose vial

REFERENCES

1. Cytogam (cytomegalovirus immune globulin intravenous [human]) [prescribing information]. Kankakee, IL: CSL Behring LLC; September 2022.
2. Preiksaitis JK, Brennan DC, Fishman J, et al. Canadian society of transplantation consensus workshop on cytomegalovirus management in solid organ transplantation final report. Am J Transplant. 2005 Feb;5(2):218-27.
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.
4. Kotton CN, Kumar D, Caliendo AM, Asberg A, Chou S, Danziger-Isakov L, Humar A, Transplantation Society International CMV Consensus Group; Transplantation. 2013;96(4):333. American Society of Transplantation – 2013
5. Kwon, S., Jung, B. K., Ko, S.-Y., Lee, C. K., & Cho, Y. (2015). Comparison of Quantitation of Cytomegalovirus DNA by Real-Time PCR in Whole Blood with the Cytomegalovirus Antigenemia Assay. Annals of Laboratory Medicine,35(1), 99–104. doi:10.3343/alm.2015.35.1.99
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
7. Snydman DR, Werner BG, Heinze-Lacey BH, et al. Use of cytomegalovirus immune globulin to prevent cytomegalovirus disease in renal transplant recipients. N Engl J Med 1987;317:1049-1054.
8. Razonable, R. R., & Humar, A. (2019). Cytomegalovirus in solid organ transplant recipients—guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clinical Transplantation, 33(9). doi:10.1111/ctr.13512
9. Kotton, C. N., Kumar, D., Caliendo, A. M., Huprikar, S., Chou, S., Danziger-Isakov, L., & Humar, A. (2018). The Third International Consensus Guidelines on the management of cytomegalovirus in solid-organ transplantation. Transplantation, 102(6), 900-931. doi:10.1097/tp.0000000000002191

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q1 2025

REVISION- Notable revisions: Required Medical Information Coding/Billing Information References	Q1 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Prescriber Requirements Contraindications/Exclusions/Discontinuation References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file