Clinical Policy: Cytomegalovirus Immune Globulin (CytoGam)

Reference Number: CP.PHAR.277
Effective Date: 09.01.18
Last Review Date: 08.20 Coding Implications
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Cytomegalovirus immune globulin (CytoGam®) is an intravenous immune globulin (IVIG) containing antibody to cytomegalovirus (CMV).

FDA Approved Indication(s)

CytoGam 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-IVIG should be considered in combination with ganciclovir.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that CytoGam is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. CMV Prophylaxis (must meet all)**:**

1. Prescribed for prophylaxis of CMV disease associated with transplantation of kidney, lung, liver, pancreas, or heart;
2. Prescribed by or in consultation with an immunologist, nephrologist, pulmonologist, hepatologist, gastroenterologist, cardiologist, or transplant specialist;
3. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 16 weeks

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. CMV Prophylaxis

1. Reauthorization beyond 16 weeks is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 16 weeks (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CMV: Cytomegalovirus
FDA: Food and Drug Administration
IVIG: intravenous immune globulin

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of a prior severe reaction associated with the administration of this or other human immunoglobulin preparations. Persons with selective immunoglobulin A deficiency have the potential for developing antibodies to immunoglobulin A and could have anaphylactic reactions to subsequent administration of blood products that contain immunoglobulin A, including Cytogam.
- Boxed Warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prophylaxis of CMV disease in kidney transplant	Initial dose (within 72 hrs of transplant): 150 mg/kg/dose IV At 2, 4, 6, and 8 weeks after transplant: 100 mg/kg/dose IV At 12 and 16 weeks after transplant: 50 mg/kg/dose IV	See regimen
Prophylaxis of CMV disease in	Initial dose (within 72 hrs of transplant): 150 mg/kg/dose IV	See regimen

Indication	Dosing Regimen	Maximum Dose
liver, lung, pancreas, or heart transplant	At 2, 4, 6, and 8 weeks after transplant: 150 mg/kg/dose IV At 12 and 16 weeks after transplant: 100 mg/kg/dose IV	

VI. Product Availability

Vial for intravenous injection: 50 mg/mL

VII. References

1. CytoGam Prescribing Information. Kankakee, IL: CSL Behring, LLC; May 2018. Available at http://labeling.cslbehring.com/PI/US/Cytogam/EN/Cytogam-Prescribing-Information.pdf. Accessed May 11, 2020.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0850	Injection, cytomegalovirus immune globulin intravenous (human), per vial

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q2018 annual review: new policy created- policy split from CP.PHAR.103 Immune globulins into individual policy for CytoGam; specialist requirement was added; references reviewed and updated.	05.15.18	08.18
3Q 2019 annual review: added commercial and HIM-Medical Benefit lines of business; no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: changed HIM-Medical Benefit to HIM line of business; no significant changes; references reviewed and updated.	05.11.20	08.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.