Clinical Policy: Cytomegalovirus Immune Globulin (CytoGam)

Reference Number: ERX.SPA.243
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 16 weeks (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 liver, lung, pancreas, or heart transplant	Initial dose (within 72 hrs of transplant): 150 mg/kg/dose IV 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	See regimen

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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: split from CP.PHAR.103 Immune globulins into individual CytoGam policy; no significant changes; specialist requirement added; references reviewed and updated.	05.15.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.11.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.10.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.