Clinical Policy: Cytomegalovirus Immune Globulin (CytoGam)

Reference Number: PA.CP.PHAR.277
Effective Date: 10.17.18
Last Review Date: 07/17/19

Coding Implications
Revision Log

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 PA Health & Wellness® 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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. CMV Prophylaxis:
Reauthorization beyond 16 weeks is not permitted. Members will need to be re-evaluated against the initial approval criteria.

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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

1. 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 – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CMV: Cytomegalovirus
FDA: Food and Drug Administration
IVIG: immune globulin (IV route)

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications
Not applicable

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. King of Prussia, PA: CSL Behring, LLC; August 2012. Available at http://labeling.cslbehring.com/PI/US/Cytogam/EN/Cytogam-Prescribing-Information.pdf. Accessed May 15, 2018.

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
Policy Created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	