




Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	Submission Date: 08/01/2024
Policy Number: PA.CP.PHAR.277	Effective Date: 10/2018 Revision Date: 07/2024
Policy Name: Cytomegalovirus Immune Globulin (CytoGam)	
Type of Submission – <u>Check all that apply:</u> <input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review - No Revisions <input type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i>	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.	
Please provide any changes or clarifying information for the policy below: 3Q 2024 annual review: no significant changes; references reviewed and updated.	
Name of Authorized Individual (Please type or print): Craig A. Butler, MD MBA	Signature of Authorized Individual: 

Clinical Policy: Cytomegalovirus Immune Globulin (CytoGam)

Reference Number: PA.CP.PHAR.277

Effective Date: 10/2018

Last Review Date: 07/2024

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 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 PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.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 policy – PA.CP.PMN.53.

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

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

Single-dose vial: 50 mg/mL

VII. References

1. CytoGam Prescribing Information. Kankakee, IL: CSL Behring, LLC; September 2022. Available at <https://cytogam.com/wp-content/uploads/2023/03/Cytogam-USA-PI-Feb-2023.pdf>. Accessed May 10, 2024.

2. Reasonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients – guidelines of the American Society of Transplantation infectious diseases community of practice. *Clinical Transplantation*. Feb 2019;33:e13512. <https://doi.org/10.1111/ctr.13512>.

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
Policy Created	10/2018
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019
3Q 2020 annual review: references reviewed and updated.	07/2020
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021
3Q 2022 annual review: no significant changes; references reviewed and updated	07/2022
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023
3Q 2024 annual review: no significant changes; references reviewed and updated.	07/2024