

PA Criteria	Criteria Details																																
Description	CYTOGAM [®] (CMV-IVIG) is an immunoglobulin G (IgG) containing a standardized amount of antibody to Cytomegalovirus (CMV).																																
Covered Uses (FDA approved indication)	<p>Cytomegalovirus IVIG (Human) is indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart.</p> <p>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.</p>																																
Dosing and Administration	<table border="1"> <thead> <tr> <th>Indication</th> <th colspan="2">Dosing Regimen</th> <th>Maximum Dose</th> </tr> </thead> <tbody> <tr> <td rowspan="8">Kidney, Lung, Liver, Pancreas and Heart Transplantation (CMV prophylaxis)</td> <td>Dose Administration POST transplant</td> <td colspan="2">Dose based on Type of Transplant</td> </tr> <tr> <td></td> <td>Kidney</td> <td>Liver/Pancreas/ Lung/Heart</td> </tr> <tr> <td>72 hours</td> <td>150 mg/kg</td> <td>150 mg/kg</td> </tr> <tr> <td>2 weeks post</td> <td>100 mg/kg</td> <td>150 mg/kg</td> </tr> <tr> <td>4 weeks post</td> <td>100 mg/kg</td> <td>150 mg/kg</td> </tr> <tr> <td>6 weeks post</td> <td>100 mg/kg</td> <td>150 mg/kg</td> </tr> <tr> <td>8 weeks post</td> <td>100 mg/kg</td> <td>150 mg/kg</td> </tr> <tr> <td>12 weeks post</td> <td>50 mg/kg</td> <td>100 mg/kg</td> </tr> <tr> <td>16 weeks post</td> <td>50 mg/kg</td> <td>100 mg/kg</td> </tr> </tbody> </table> <p>Initial infusion rate: start at 15 mg/kg/hr; if tolerated after 30 minutes, rate may be increased to 30 mg/kg/hr</p> <ul style="list-style-type: none"> If tolerated after subsequent 30 minutes, infusion may be increased to target MAX of 60 mg/kg/hr <p>Subsequent doses: start infusion at 15 mg/kg/hr for 15 minutes. If well tolerated, increase to 30 mg/kg/hr for 15 min. If well tolerated, increase to target MAX of 60 mg/kg/hr (do not exceed 75 mL/hr).</p>	Indication	Dosing Regimen		Maximum Dose	Kidney, Lung, Liver, Pancreas and Heart Transplantation (CMV prophylaxis)	Dose Administration POST transplant	Dose based on Type of Transplant			Kidney	Liver/Pancreas/ Lung/Heart	72 hours	150 mg/kg	150 mg/kg	2 weeks post	100 mg/kg	150 mg/kg	4 weeks post	100 mg/kg	150 mg/kg	6 weeks post	100 mg/kg	150 mg/kg	8 weeks post	100 mg/kg	150 mg/kg	12 weeks post	50 mg/kg	100 mg/kg	16 weeks post	50 mg/kg	100 mg/kg
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Product Availability	<i>Single-dose vial:</i> 50 mg/mL; preservative-free																																

Contraindications	<ul style="list-style-type: none"> History of severe hypersensitivity to cytomegalovirus immune globulin IV (human), other human Ig preparations, or any component of the formulation. Selective Ig A deficiency.
Recommended Medical Monitoring	<p>CYTOGAM has been associated with:</p> <ul style="list-style-type: none"> Hypersensitivity reactions, including anaphylaxis Aseptic meningitis syndrome (AMS) Hemolysis/Hemolytic anemia Pulmonary edema/transfusion-related acute lung injury (TRALI) Renal impairment/acute renal failure Thrombotic events Hypovolemia
Approval Criteria	<p>A. Physician administered IV infusion; in-office or HOPD</p> <p>i. Cannot be self-administered</p> <p>B. CMV Prophylaxis (must meet all):</p> <p>i. Prescribed for prophylaxis of CMV disease associated with transplantation of kidney, lung, liver, pancreas, or heart;</p> <p>ii. Prescribed by or in consultation with an immunologist, nephrologist, pulmonologist, hepatologist, gastroenterologist, cardiologist, or transplant specialist;</p> <p>iii. Dose does not exceed maximum dose indicated in dosing above.</p> <p>C. Approval duration: 16 weeks</p>
Age Restriction	None.
Coverage Duration	<p>Total Coverage Duration: 16 weeks post-transplantation</p> <p>Reauthorization beyond 16 weeks is NOT permitted.</p> <p>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</p>
Other Criteria (LCD, NCD, etc.)	Must follow LCD L34314 for Immune Globulin Intravenous (IVIG)
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	4/14/26	4/14/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	5/14/26	Pharmacy & Therapeutics (P&T) Committee	5/14/26