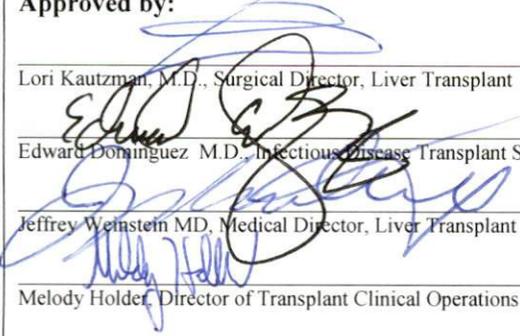


 <b>Methodist Dallas Medical Center</b>	<b>Title:</b> CMV Protocol	<b>Effective Date:</b> 02/19/2003
	<b>Section:</b> Liver	
<b>Approved by:</b> 		<b>Revision Date(s):</b> 09/ 12/2007; 1/22/2009; 03/25/2009; 10/22/2015; 02/20/2017; 02/10/2020; 6/2021; 05/11/2022; 01/18/2024; 04/01/2025; 06/26/2025
Lori Kautzman, M.D., Surgical Director, Liver Transplant Edward Dominguez M.D., Infectious Disease Transplant Services Jeffrey Weinstein MD, Medical Director, Liver Transplant Melody Holder, Director of Transplant Clinical Operations		<b>Next review Date:</b> 06/2028

**Purpose:** To ensure consistent testing and treatment of liver transplant recipients at risk for CMV infection

**Policy:** All potential transplant recipients will have CMV IgG testing during the transplant evaluation All deceased and living donors will also have CMV IgG testing performed per OPTN policy.

An equivocal serologic assay result in the donor should be assumed to be positive, whereas in the recipient this result should be interpreted to assign the recipient to the highest appropriate CMV risk group for post transplantation management decisions <sup>1</sup>.

**Procedure:**

Outpatient CMV labs to be drawn with Monday labs if possible

**Liver Transplant:**

**CMV negative recipients of CMV negative donors**

- No prophylaxis
- CMV PCR drawn on admission for transplant then weekly up to week 12 post transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of PCRs to 12 weeks

**CMV negative recipients of CMV positive donors**

- Universal prophylaxis for 180 days post-transplant
- Valcyte 900 mg PO daily or Ganciclovir 5 mg/kg IV daily (if unable to take PO) - adjust for renal function per "Antimicrobial Renal Dosing Guidance" protocol
- After Prophylaxis, screen CMV PCR monthly until one year post-transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of prophylaxis for 180 days.

### **CMV positive recipients of CMV negative donors**

- No prophylaxis
- Routine CMV PCR to be drawn on admission for liver transplant then weekly upon discharge up to week 12 post- transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of PCRs to 12 weeks

### **CMV positive recipients of CMV positive donors**

- No prophylaxis
- Routine CMV PCR to be drawn on admission for liver transplant then weekly up to week 12 post -transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of PCRs to 12 weeks

### **Combined liver/Kidney Transplant and HIV Positive Recipient:**

#### **CMV negative recipients of CMV negative donors**

- No prophylaxis
- CMV PCR drawn on admission for transplant then weekly up to week 12 post- transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of PCRs to 12 weeks

#### **CMV negative recipients of CMV positive donors**

- Universal prophylaxis for 180 days post-transplant
- Valcyte 900 mg PO daily or Ganciclovir 5 mg/kg IV daily (if unable to take PO) - adjust for renal function per "Antimicrobial Renal Dosing Guidance" protocol
- After Prophylaxis, screen CMV PCR monthly until one year post-transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of treatment for 180 days.

#### **CMV positive recipients of CMV negative donors**

- Universal prophylaxis for 90 days post-transplant
- Valcyte 900 mg PO daily or Ganciclovir 5 mg/kg IV daily (if unable to take PO) - adjust for renal function per "Antimicrobial Renal Dosing Guidance" protocol
- After Prophylaxis, screen CMV PCR monthly until one year post-transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of treatment for 90 days.

#### **CMV positive recipients of CMV positive donors**

- Universal prophylaxis for 90 days post-transplant
- Valcyte 900 mg PO daily or Ganciclovir 5 mg/kg IV daily (if unable to take PO) - adjust for renal function per "Antimicrobial Renal Dosing Guidance" protocol
- After Prophylaxis, screen CMV PCR monthly until one year post-transplant
- In patients treated with a steroid recycle or thymoglobulin for rejection, restart/extend duration of treatment for 90 days.

**Patients who receive Thymoglobulin/Simulect induction, treatment for AMR, or who are treated for rejection with Thymoglobulin:**

- Universal prophylaxis at initiation of therapy and for 180 days thereafter
- Valcyte 900 mg PO daily or Ganciclovir 5 mg/kg IV daily (if unable to take PO) - adjust for renal function per "Antimicrobial Renal Dosing Guidance" protocol
- After prophylaxis, screen CMV PCR monthly until one year post Thymoglobulin or Simulect therapy

\*CMV PCR will be drawn per above protocol and based on patient symptoms and clinical suspicion.  
**Consider therapy when CMV PCR reveals > 1000 IU** (international units)

- Please note:  
**Changes in viral load exceeding 0.5 log<sub>10</sub> IU/mL (threefold) are considered to represent clinically significant differences in DNAemia and may consider treating candidates especially if CMV PCR is less than 1000 IU<sup>2</sup>.**
- **Any levels of DNAemia (even if <1000 IU) should be reviewed with ID physician. A Cr and GFR level should be included**
- Antiviral treatment dosing should be continued for a minimum of two weeks, until clinical resolution of disease and eradication of CMV DNAemia below a specific threshold (LLOQ less than 200 IU/mL) on one or two consecutive weekly samples<sup>2</sup>.
- Drug resistance should be suspected in patients with a prior cumulative (val)ganciclovir exposure that exceeds six weeks and clinical treatment failure despite at least two weeks of antiviral treatment or development of CMV DNAemia during prophylaxis<sup>2</sup>.

<b>When to get a CMV TCIP</b>	1 week from CMV DNAemia clearance
<b>How to interpret CMV TCIP Results</b>	
CD4 ≥ 0.20% AND CD8 ≥ 0.20%	Discontinue secondary prophylaxis of valganciclovir
CD4 ≥ 0.20% but CD8 < 0.20%	
CD8 ≥ 0.20% but CD4 < 0.20%	Continue valganciclovir secondary prophylaxis Recheck CMV TCIP in 4 – 6 weeks
CD4 < 0.20%	
CD8 < 0.20%	

### Valcyte Dosing Guideline

- 1.) Valcyte (valGANCiclovir) is dosed off of creatinine clearance NOT eGFR. There are online calculators that can help you calculate it or you can always reach out to pharmacy for help (Alicia Reeve, Erin Loncharic or Jessica Crotty)
- 2.) Treatment dosing is for patient with active CMV. This is the dose we start when someone has a CMV PCR >1000 IU/mL and continue until their CMV has resolved.
- 3.) Prophylaxis is the dose we put patients on to prevent CMV and is typically used immediately post-transplant. Prophylaxis dosing can also be used in select patients after CMV has resolved.
- 4.) Be careful Valcyte (valGANCiclovir) is a look alike sound alike with Valtrex (ValACYclovir) so always double check you have picked the right drug

Valcyte (ValGANCiclovir)	Creatinine Clearance (mL/min)	Dose adjustment
<b>TREATMENT (AKA Induction)</b> Standard dose 900mg BID	>60	900mg BID
	40-59	450mg BID
	25-39	450 mg QD
	10-24	450mg every 48 hours (ie every other day)
	<10 or HD	200mg 3x/week after HD **Requires liquid product
<b>PROPHYLAXIS (AKA maintenance)</b> Standard dose 900mg QD	>60	900mg QD
	40-59	450mg QD
	25-39	450mg every 48 hours (ie; every other day)
	10-24	450mg twice weekly
	<10 or HD	100mg 3x/week after HD **Requires liquid product

References:

1. Preiksaitis JK, Sandhu J, Strautman M. The risk of transfusion-acquired CMV infection in seronegative solid organ transplant recipients receiving non-WBC-reduced blood components not screened for CMV antibody (1984 to 1996): experience at a single Canadian center. *Transfusion* 2002;42:396-402.
2. Kotton CN, Kumar D, Caliendo AM, et al. The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation. *Transplantation* 2018;102:900-931
3. Kotton CN, Kumar D, Caliendo AM, Huprikar S, Chou S, Danziger-Isakov L, Humar A; The Transplantation Society International CMV Consensus Group. The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation. *Transplantation*. 2018 Jun;102(6):900-931. doi: 10.1097/TP.0000000000002191. PMID: 29596116.