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| **POLICY TITLE: Kidney/Pancreas Post Transplant: CMV Protocol**  |
| **APPLICABLE FACILITIES:** (Check all that apply) [x] EUH [ ] EUOSH [ ] EWWH [ ] EUHM [ ] EJCH [ ] ESJH [x] TEC [ ] ESA [ ] ERH |
| **EFFECTIVE DATE:** 9/12/2018 | **ORIGINATION DATE:** 9/26/2007 |

**SCOPE:** All transplant program physicians, practitioners and clinical staff members are responsible for compliance with this clinical protocol.

**PURPOSE:** This protocol is necessary for the protection of patients, physicians and staff

**POLICY STATEMENT:** The Emory Transplant Center and all the solid organ transplant programs will comply with all applicable federal, state, and local laws, regulations, policies and protocols regarding the management of transplant patients.

**PROCEDURE:**

1. All patients undergoing kidney and/or pancreas transplantation will have the CMV status (antibody) rechecked at the time of transplantation.

2. CMV status of donor and recipient will be documented in EeMR.

3. **Prophylaxis post transplant** (for eGFR >60 ml/min):

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| --- | --- | --- |
| Donor/Recipient Status | Prophylaxis Regimen | Duration |
| D+/R- | Valganciclovir 900 mg po daily | 6 months |
| Any R+ | Valganciclovir 450 mg po daily | 3 months |
| D-/R- | Valacyclovir 1000 mg po daily | 3 months |

Note: D = donor, R = recipient, (+) = positive, and (-) = negative

Dosage adjustment for renal function is as follows:

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| --- | --- | --- | --- |
| eGFR >60 (ml/min) | Valganciclovir 900 mg daily | Valganciclovir 450mg daily | Valacyclovir 1000mg daily |
| 40-59 | 450mg daily | 450mg daily (no change | 1000mg daily (no change) |
| 10-39 | 450mg po 3 times/week | 450mg po 3 times/week | 500mg po daily |
| < 10 or dialysis dependent | 450mg po post-hemodialysis or 2-3 times/week | 450mg po post-hemodialysis or 2-3 times/week | 500mg po daily, administer post-hemodialysis on HD days |

4. Patients unable to take oral medication may be given ganciclovir 5 mg/Kg IV daily (adjusted for renal function) or have weekly CMV PCRs checked until able to take oral medication.

5. CMV Monitoring by PCR testing

A. **D+/R-** and **R+** patients

i. Monthly by CMV PCR

ii. CMV PCR will be discontinued after the 12 month draw unless clinically indicated

B. **D-/R-**

i. No per protocol testing

C. **Rejection**

i.CMV PCR will be drawn monthly for months 1 – 6 following each documented rejection episode treated with T cell depleting antibody

D. **CMV PCR** will be performed, in addition to above, when CMV disease is suspected and when clinically indicated.

6. **Treatment of CMV Disease:**

1. **CMV positive recipients (R+)**
2. Patients with CMV PCR > 1000 should receive treatment, regardless of the presence of symptoms.
3. Patients with CMV PCR < 1000 should have the test repeated in 1-2 weeks and do not require immediate treatment.
4. Patients with CMV PCR < 1000 and confirmed/suspected CMV disease should undergo treatment.
5. **CMV negative recipients (R-)**
	1. Patients with a detectable CMV PCR (including < 35 IU/mL) should undergo treatment.
6. **Treatment of Choice**
	1. Patients with severe disease, including most patients with tissue invasive CMV disease, should be initially treated with intravenous Ganciclovir.
	2. CMV disease with mild clinical symptoms or asymptomatic viremia may be treated with oral Valganciclovir.
7. **Duration of Treatment & Monitoring**
	1. Therapy should be continued for at least 21 days AND until at least 2 consecutive undetectable CMV PCR tests at least 1 week apart.
	2. Patients should have a CMV PCR checked weekly while on treatment.
	3. Consider ophthalmology exam in patients with recurrent or resistant CMV.
8. **Prophylaxis after Treatment**
	1. May be considered in the select patients:
		1. Patients who develop CMV viremia/disease while on prophylaxis
		2. Patients with tissue invasive disease
		3. Patients with recurrent CMV viremia/disease
		4. Patients who are high risk for CMV (D+/R-)
		5. Patients who have received Thymoglobulin within the last 6 months

Once treatment ends, PCR surveillance will continue monthly for 3 months after treatment or prophylaxis is discontinued.

**Treatment Dosing Recommendations**:

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| eGFR (ml/min) | Valganciclovir (mg) – Oral | Ganciclovir (mg) - IV |
| > 60 | 900 mg po q12h | 5 mg/Kg IV q 12 hours |
| 40-59 | 450 mg po q12h | 2.5 mg/Kg IV q 12 hours |
| 25-39 | 450 mg po daily | 2.5 mg/Kg IV daily |
| 10-24 | 450 mg po every other day | 1.25 mg/Kg IV daily |
| <10 or dialysis dependent | 450 mg po post dialysis or 3 times per week | 2.5 mg/Kg IV post dialysis or 3 times per week |

**Prophylaxis after Treatment:**

|  |  |
| --- | --- |
| eGFR (ml/min) | Valganciclovir (mg) – Oral |
| > 60 | 900 mg po daily |
| 40-59 | 450 mg po daily |
| 10-39 | 450 mg po 3 times per week |
| <10 or dialysis dependent | 450 mg po post dialysis or 3 times per week |

7. **Post T Cell Depleting Antibody Therapy:**

All recipients who receive T cell depleting antibody therapy for a rejection episode should receive 3-6 months of prophylaxis with valganciclovir or valacyclovir (see dosing as outlined in #3).

CMV PCR will be drawn monthly for months 1 – 6 following each documented rejection episode treated with T cell depleting antibody

8. **Transplant ID Clinic**

Selected patients treated for CMV infection may be referred for follow up in the Transplant ID Clinic.

Patients with resistant CMV or those treated with second or third line agents should be followed in Transplant ID clinic

9. **Leukopenia:** Do **NOT** reduce the dose of valganciclovir or ganciclovir for leukopenia.

i. If Absolute Neutrophil Count (ANC) drops below 500, consider administration of G-CSF (Neupogen/Granix) until ANC > 500

ii. If patient is not a candidate for G-CSF administration, then consider placing patient on pre-emptive strategy

10. **Policy Review:**

As part of the QAPI program, policy compliance and CMV viremia rates for the first twelve months post transplant will be reviewed every six months by the transplant program’s clinical leadership and transplant infectious disease specialist.

**RELATED DOCUMENT(S)/LINK(S):**

N/A

**DEFINITIONS:** *(If applicable)*

N/A

**REFERENCES AND SOURCES OF EVIDENCE:**

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**KEY WORDS:** Cytomegalovirus, CMV, valganciclovir, ganciclovir

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| **REVIEW/APPROVAL SUMMARY:** Please select all Approving Bodies: |
| [ ] EUH MEC [ ]  EUHM MEC [ ] ESJH MEC [ ] EJCH MEC [ ] CNE Council [ ] System Operations |
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