EMORY
HEALTHCARE

PROTOCOL TITLE: Eculizumab for Severe Antibody Mediated Rejection Protocol for Heart Transplant Recipients							
APPLICABLE FACILITIES:							
☒EHC	☐EDH	☐EHH	☐EHI	☐EHN	☐EJCH	☐ELTAC	☐ESJH
☒EUH	☐EUHM	☐EUHS	☐EUOSH	☐EWWH	☐RJV-ERH	☐RJV-ESOP	☐TEC/ESA
EFFECTIVE DATE: 5/4/2020				**ORIGINATION DATE:** 8/4/2022			

CATEGORY:
Choose One or More: Medication Guidelines

LEVEL:
Choose One: Interdependent

CONTENT: This protocol applies to heart transplant recipients who are determined to acute cellular rejection.

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.

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

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

RELATED POLICIES / PROCEDURES:

Initial assessment:

Commented [HM1]: Do we want to include rejection grade?

1. In order to proceed to this therapy, the patient must have hemodynamic compromise and at least 1 of the following:
    a. High suspicion of Antibody Mediated Rejection (AMR)
    b. documented Donor Specific Antibodies (DSA)
    c. biopsy-proven AMR
2. Exclusion to consideration for therapy:
    a. Documented or high suspicion for infection
1. If the patient requires plasmapheresis, please give dose after plasmapheresis has been done for the day or after course of plasmapheresis has been completed if able to delay administration for several days
    a. T1/2 is 8-15d but only 1.26 hrs after plasma exchange
    b. If the patient would benefit from IVIG, consider treating with that first and then consider starting eculizumab the day after the IVIG infusion is complete if able to wait.
        i. **IVIG decreases efficacy of eculizumab**
        ii. **Rituximab should be avoided due to its neutralizing effects on eculizumab**

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2. Please contact transplant PharmD to assist with getting medication ordered as it is non-formulary
3. Requires *Neisseria Meningitis* antibiotic prophylaxis at time of initial eculizumab therapy and continue for a minimum of 2 weeks post the last provided dose unless the patient received Meningococcal vaccine at least 2 weeks prior to eculizumab therapy. Prophylaxis can be accomplished with PenVK 500mg BID, renally dosed if pt is not penicillin allergic. Discuss alternatives with transplant ID if penicillin allergic.

4. Pre-medications: None required

5. Please make certain post-transplant HLAs have been drawn prior to initial eculizumab dose

6. Please infuse over 35 min regardless of dose being used

7. Sample AMR treatment regimen with eculizumab:

    a. Plex x 5 doses + pulse steroids + IVIG (per AMR protocol)
        i. Day 0 -> Eculizumab 1200mg
            1. Day after IVIG administration if given
            2. Otherwise day of initial dose
        ii. Day 1 -> Eculizumab 900 mg
        iii. Day 7 -> Eculizumab 900 mg
        iv. Day 14 -> Eculizumab 900 mg
        v. Day 21 -> Eculizumab 900 mg
        vi. Day 28 -> Eculizumab 1200 mg
        vii. Day 42 -> Eculizumab 1200 mg
        viii. Day 56 -> Eculizumab 1200 mg

DEFINITIONS:

Plex – plasma exchange
IVIG – IV immunoglobulin

REFERENCES AND SOURCES OF EVIDENCE:

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KEY WORDS:
Heart Transplant
Severe Rejection
Immunosuppression