TO: YNHHS MEDICAL STAFF, PHARMACY STAFF, AND NURSING
FROM: YNHHS COVID-19 TREATMENT TEAM
YNHHS AD-HOC BLOOD BANK TEAM FOR CONVALESCENT PLASMA
YNHHS ANTIMICROBIAL STEWARDSHIP COMMITTEE

SUBJECT: COVID-19 Convalescent Plasma (CCP)

DATE: November 18, 2020

S: There is a need to update the recommendations for the use of COVID-19 convalescent plasma (CCP) in patients with COVID-19 at YNHHS.

B: On August 23, the FDA issued an Emergency Use Authorization for CCP as a potential COVID–19 treatment. This recommendation was based on observational data obtained from the Mayo Expanded Access Program, from which it was concluded that CCP potentially confers benefit when used early in the disease course of COVID-19.

CCP remains an investigational treatment, as emphasized in the EUA announcement. There have not been any robust randomized placebo-controlled studies demonstrating benefit of CCP. Two studies were ended early due to decreased number of patients with COVID-19 and the presence of adequate titers of anti-SARS-CoV-2 in patients with COVID-19 at baseline. In addition, CCP remains a scarce resource and will be for the foreseeable future.

A: There is a need to obtain robust data on the efficacy of CCP and to prioritize patients who might gain benefit from receiving this investigational treatment as well as to optimize the ordering of convalescent plasma for COVID-19 patients.

R: Based on input from the Ad hoc COVID-19 Treatment Team YNHHS Antimicrobial Subcommittee, and the YNHH Blood Bank Team for CCP, the following procedures for CCP should be followed.

1) **YNHH, York Street Campus Only at this time:**

   Patients who are being considered for CCP, should be reviewed for enrollment in the randomized clinical trial for CCP (https://www.ynhhs.org/patient-care/covid-19/for-employees/for-employees.aspx)

   Exclusion Criteria include:

   A) Patients beyond 3 days of hospitalization

   B) Patients who are mechanically ventilated despite meeting criterion 1.

2) **For GH, BH, LMH, WH, YNHH-SRC, and YNHH-YSC Campus (who do not meet criteria for the above CCP RCT):**

   For patients who do not meet criteria for enrollment in the randomized clinical trials (i.e. patients on mechanical ventilation or patients beyond 3 days of hospitalization) or for patients hospitalized in a hospital where the RCT cannot be implemented, it should be realized that CCP remains an investigational treatment.
1. If CCP is being considered, the patient must meet the following 2 criteria:
   • Patient has a confirmed positive SARS-CoV-2 PCR result
   AND
   • Patient has been admitted for ≤ 6 days
   AND
   • Patient requires ≥ 3 liters of oxygen supplementation

2. Patients who meet these any of the following criteria should be excluded:
   A: History of anaphylaxis to blood products or history of IgA deficiency
   B. D-dimer > 10
   C. Evidence or suspicion of thrombosis
   D. Active bleed or high risk for bleeding

3. Any patient who receives this investigational therapy should receive, at minimum, intermediate dose prophylaxis anticoagulation with enoxaparin for 72 hours, regardless of d-dimer. After 72 hours, the need for intermediate dose prophylaxis can be re-assessed based on d-dimer level and risk for thrombosis.

4. To order CCP outside of the clinical trial, effective 11/18/2020, use the following order in EPIC entitled: “Evaluation for COVID-19 Convalescent Plasma (CCP)”:  

   The above order will trigger a pharmacist review for the CCP to determine if the patient meets YNHHS Criteria for use.

   NOTE: Since CCP must be ordered from a regional blood center by the blood bank, the consult for CCP will be evaluated from 7AM to 4PM during the business hours of regional blood centers.