

COVID-19

Interim 90-day Guidance for Clinicians on the Use of COVID-19 Convalescent Plasma

On Aug 23, 2020, the U.S. FDA approved the use of COVID-19 Convalescent Plasma (CCP) under an Emergency Use Authorization (EAU) as passive immune therapy for the treatment of hospitalized patients with COVID-19. Limited data suggests that treatment early (<3 days) in the course of disease (prior to intubation) would be expected to have more benefit. However, adequate and well-controlled randomized trials have not been performed, and the most recent COVID-19 NIH Treatment Guidelines (dated Sep 1, 2020) advise that “there are insufficient data to recommend either for or against the use of convalescent plasma for the treatment of COVID-19”. In addition, although the FDA reported that there is some evidence to suggest that CCP with higher antibody content may be more likely to be effective, at this time most of the available CCP does not have a quantitative antibody titer. It is expected that over the next 3 months, COVID-19 Convalescent Plasma with quantitative antibody testing will be more widely available and updated guidance for clinicians will follow.

Should clinicians decide to administer CCP, the following guidance is suggested:

1. CCP should be reserved for hospitalized patients who require supplemental oxygenation
2. CCP should be dosed as one CCP unit (about 200 mL), with additional dosing based on the physician’s medical judgement (for example, response to CCP or weight-based dosing)
3. Patients with impaired cardiac function/heart failure or ESRD may require a smaller volume or more prolonged transfusion times

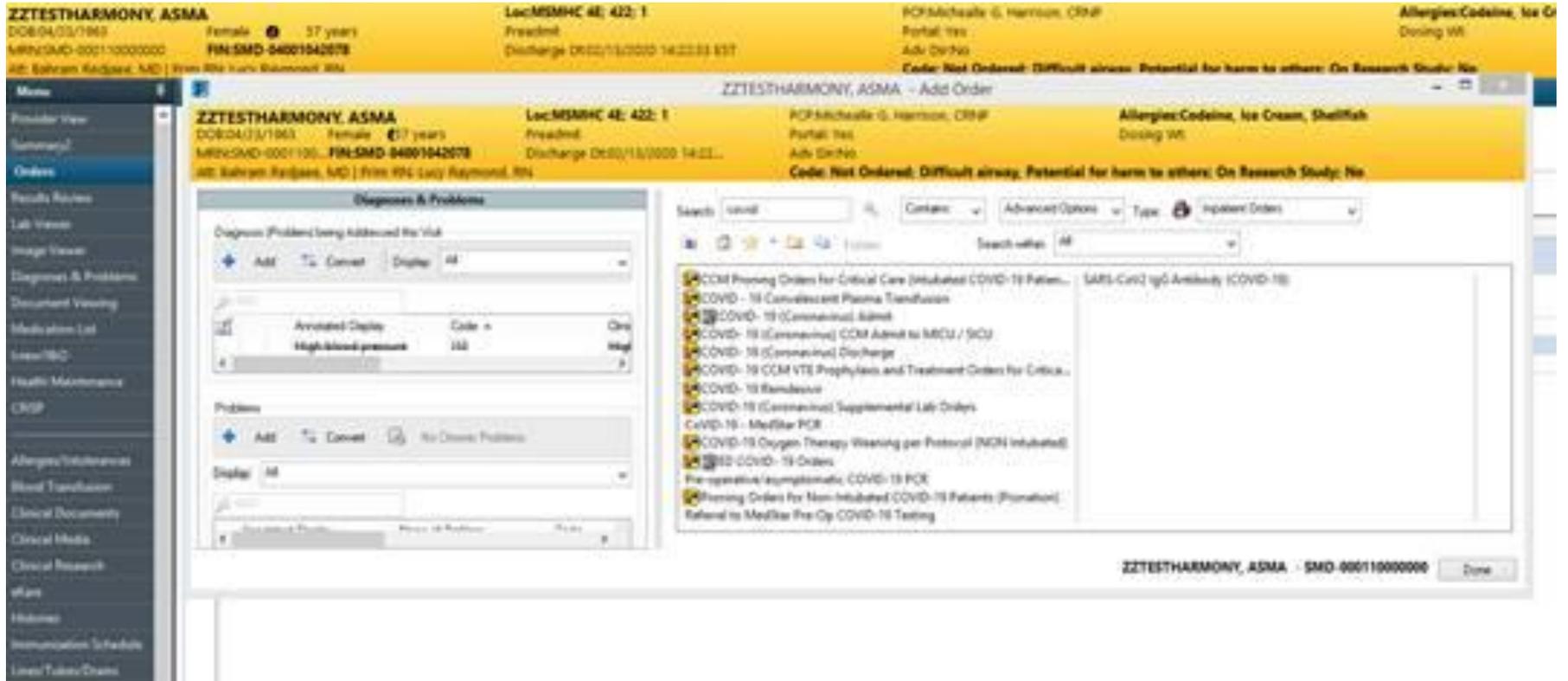
When ordering CCP, the following steps should be taken:

1. Obtain a blood type (plasma is type specific)
2. Obtain consent on a standard MedStar transfusion consent.
3. On the transfusion consent form physician/designee must write:
“The patient/caregiver was informed about the investigational nature of COVID Convalescent Plasma and were given the opportunity to ask questions. They were informed that the amount of anti-COVID antibodies present in the plasma is unknown at this time.”
4. This CCP plasma MUST be labelled “COVID Convalescent Plasma: anti-COVID antibody titer and efficacy unknown.” We are coordinating this with hospital blood banks.
5. Please order convalescent plasma as shown: **orders type covid -> select Covid-19 convalescent plasma-> in the drop box select time for transfusion and put “none” under protocol and leave registration number blank.** The system will ask you if you have obtained PI consent and say ok – this still needs to be updated. See screenshots below.



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6. Patient must receive the 'Fact Sheet for Patients' which is available on the COVID-19 website. A 'Fact sheet for Providers' is also available on the website.
7. If possible, would give Tylenol premedication to mitigate febrile transfusion reactions. Consider giving plasma over one hour , 2 hours if there is concern for volume



The screenshot displays a patient's medical record in a software interface. At the top, patient information for ZZTESTHARMONY, ASMA is shown, including DOB (04/03/1963), gender (Female), age (57 years), and MRN (SMD-00011000000). The patient is currently at LocMSMHC 4E: 422: 1. The interface includes a navigation menu on the left with options like 'Orders', 'Results Review', and 'Lab Values'. The main content area is titled 'ZZTESTHARMONY, ASMA - Add Order' and features a search bar with the text 'COVID'. Below the search bar, a list of COVID-19 related orders is displayed, including 'CCM Preop Orders for Critical Care (Intubated COVID-19 Patien...', 'COVID-19 Convalescent Plasma Transfusion', 'COVID-19 (Coronavirus) Admit', 'COVID-19 (Coronavirus) CCM Admit to MICU / SICU', 'COVID-19 (Coronavirus) Discharge', 'COVID-19 CCM VTE Prophylaxis and Treatment Orders for Critica...', 'COVID-19 Bandages', 'COVID-19 (Coronavirus) Supplemental Lab Orders', 'COVID-19 - MedStar PCR', 'COVID-19 Oxygen Therapy Weaning per Protocol (NON Intubated)', 'COVID-19 Orders', 'Pre-operative/asymptomatic COVID-19 PCR', and 'Preop Orders for Non-Intubated COVID-19 Patients (Promote)'. A 'Done' button is visible at the bottom right of the order list.

