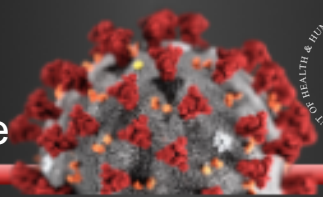

August 24, 2020

COVID-19 Convalescent Plasma
-EMERGENCY USE AUTHORIZATION-

Mechanism of Action[1]: COVID-19 Convalescent Plasma (CCP) is a blood product collected via plasmapheresis from human donors who have recovered from infection with SARS CoV-2 virus. It is a form of passive immunotherapy whose principle mechanism of action is thought to be antibody neutralization of the virus.

Current Status[2,3]: COVID-19 Convalescent Plasma is not FDA approved. On August 23, 2020, the U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) for CCP. Use is permitted as a passive immune therapy for the treatment of hospitalized patients with COVID-19. ***Current evidence suggests clinical benefit is most likely in patients treated early in the course of the disease (e.g., prior to intubation) and with the use of CCP with higher antibody levels or neutralization activity.***

Availability: CCP is obtained from registered and licensed blood banks that collect plasma intended for transfusion. Blood products are not available through the IHS National Supply Service Center or the Pharmacy Prime Vendor (PPV) program.

Efficacy[4]: ***Given that the clinical evidence supporting this EUA was not obtained from prospective, well-controlled randomized clinical trials (RCTs), additional RCTs are needed. Convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19. Ongoing clinical trials of convalescent plasma should not be amended based on the issuance of the EUA. Providers are encouraged to enroll patients in those ongoing clinical trials.***

Recommended Dosing[4]: Current recommendations are for a single unit (approximately 200ml) of ABO-compatible CCP according to standard hospital procedures and adjust additional units based on medical judgement and the patient's clinical response. Patients with impaired cardiac function and heart failure may require a smaller volume or more prolonged transfusion times.

Adverse Drug Events/Contraindications/Cautions[4]: The significant and potential risks are not fully known. Some of the known adverse drug events from convalescent plasma administration include transfusion-transmitted infections, allergic reactions, febrile nonhemolytic reactions, transfusion-related acute lung injury (TRALI), transfusion-associated cardiac overload (TACO), and hemolytic reactions. There are theoretical concerns that it may enhance infection or increase the risk of reinfection in the future. Use in patients who are pregnant, breastfeeding, <18 years of age, or elderly have not been evaluated. Use should be based on individual assessment of risk and benefit. COVID-19 convalescent plasma may be contraindicated in patients with a history of severe allergic reactions or anaphylaxis to plasma transfusion.

Storage[4]: Stored frozen at -18°C or colder, and has an expiration date one year from the date of collection. Once thawed, it can be refrigerated for up to 5 days prior to patient transfusion.

Guidelines[1,5]:

- According to the current Infectious Diseases Society of America Guidelines, among patients who have been admitted to the hospital with COVID-19, the IDSA guideline panel recommends COVID-19 convalescent plasma only in the context of a clinical trial.

- According to the current NIH COVID-19 Treatment Guidelines, there are insufficient data for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of COVID-19 convalescent plasma for the treatment of COVID-19.

Additional Resources[4,6]: Please review the FDA's Fact sheet for healthcare providers for more detailed information. In addition to obtaining appropriate informed consent, the FDA requires that healthcare providers administering COVID-19 Convalescent Plasma must provide recipients with the Fact Sheet for Patients and Parents/Caregivers.

References:

1. IDSA Guidelines on the Treatment and Management of Patients with COVID-19, https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-3, Accessed 8/24/20.
2. EUA Request-COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients. https://www.fda.gov/media/141480/download, Accessed 8/24/20.
3. EUA of COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients, https://www.fda.gov/media/141477/download, Accessed 8/24/20.
4. EUA of COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients- Fact Sheet for Healthcare Providers, https://www.fda.gov/media/141478/download. Accessed 8/24/20.
5. NIH COVID-19 Treatment Guidelines, https://www.covid19treatmentguidelines.nih.gov/immune-based-therapy/blood-derived-products/convalescent-plasma/, Accessed 8/24/20.
6. EUA of COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients- Fact Sheet for Patients and Parents/Caregivers, https://www.fda.gov/media/141479/download, Accessed 8/24/20.