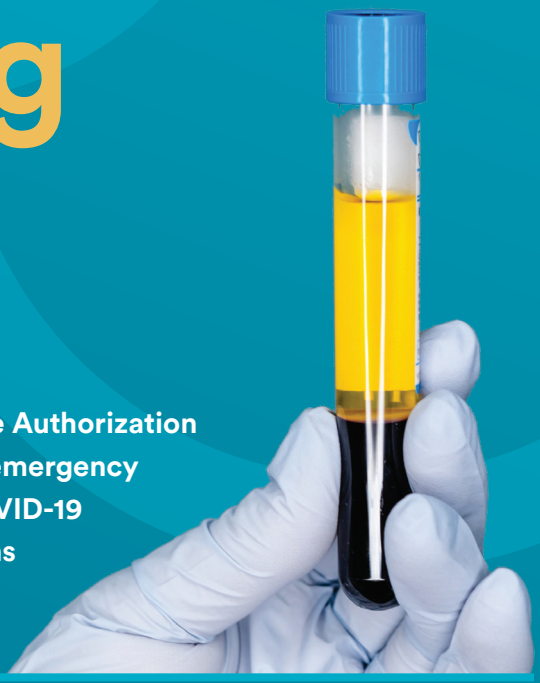
Association for the Advancement of Blood & Biotherapies

Understanding FDA's Revised Emergency Use of COVID-19 Convalescent Plasma



The Food and Drug Administration issued a revised Emergency Use Authorization on Dec. 28, 2021, that provides updated recommendations on the emergency use of high-titer COVID-19 convalescent plasma (CCP) to treat COVID-19 in certain patient populations. Here are key takeaways for clinicians considering this therapy to treat patients with COVID-19:

What is COVID-19 convalescent plasma (CCP)?

CCP is human plasma collected from individuals whose plasma contains high titers of anti-SARS-CoV-2 antibodies, as defined by FDA, for treatment of COVID-19. Blood centers are responsible for ensuring that CCP satisfies all FDA's requirements, including complex screening and testing procedures for product quality and transfusion safety.

Which patients can receive CCP under the EUA?

FDA's authorization for treatment with CCP is limited to patients with **immunosuppressive disease or receiving immunosuppressive treatment**, based on the "larger potential benefit" described in a ***Dec. 27 clinical memorandum***.**

In which settings can patients receive CCP under the EUA?

Clinicians can administer CCP to patients in both the outpatient and hospital inpatient care settings.

When should patients receive CCP?

Give CCP as early as possible for outpatients and **no later than 8 days past symptom onset.** Severely immunosuppressed inpatients may still derive benefit later in the disease course.

** Medical providers should use their medical judgment to identify patients with immunosuppressive disease or receiving immunosuppressive treatment. For example, FDA notes that case series and reports have illustrated clinical improvements of patients with immunosuppressive disease or receiving immunosuppressive treatment who have been treated with CCP, including patients with X-linked agammaglobulinemia, hematologic malignancy, stem cell transplantation, solid organ transplants, B-cell depleting therapies and common variable immunodeficiency, among other conditions.

REFERENCES

1. ***Clinical Memorandum: COVID-19 Convalescent Plasma*** *(December 27, 2021)*
2. ***Convalescent Plasma EUA Letter of Authorization*** *(December 28, 2021)*
3. ***FDA Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of COVID-19 Convalescent Plasma for Treatment of Coronavirus Disease 2019 (COVID-19)***
4. ***FDA Fact Sheet for Patients and Parents/Caregivers: Emergency Use Authorization (EUA) of COVID-19 Convalescent Plasma for Treatment of Coronavirus Disease 2019 (COVID-19)***