COVID-19

Convalescent Plasma (CP)

APRIL 14, 2020

Convalescent plasma (CP) is plasma collected from recovered COVID-19 individuals that contains antibodies to SARS-CoV-2. In order to be eligible for CP, patients must meet the following criteria (a, b, and c), according to the FDA.

A. To be **eligible** to receive convalescent plasma, **patients**:

a. Must have laboratory-confirmed COVID-19 infection
b. Must have severe or immediately life-threatening COVID-19, for example:
   i. **Severe disease** is defined as:
      1. Dyspnea
      2. Respiratory frequency ≥ 30/min
      3. Blood oxygen saturation ≤ 93%
      4. Partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300, and/or
      5. Lung infiltrates > 50% within 24 to 48 hours
   ii. **Life-threatening disease** is defined as:
      1. Respiratory failure
      2. Septic shock, and/or
      3. Multiple organ dysfunction or failure
c. Must provide informed consent

The requesting physician should follow the steps below to request convalescent plasma.

1. Complete the **FDA eIND (3926) form** **https://www.fda.gov/media/98616/download** and submit by email to **CBER_eIND_Covid-19@FDA.HHS.gov**.
2. Include a brief clinical history of the patient on the **FDA 3926 form**, including diagnosis, current therapy, and rationale for requesting the proposed investigational treatment, in order to meet the expanded access use requirements of 21 CFR 312.305 and 312.310. The **COVID-19 convalescent plasma will be obtained at Arkansas Blood Institute**.
3. The FDA will review the request and, upon approval, will send the requesting physician a confirmatory email that includes the emergency IND number. **Forward the eIND number immediately to the UAMS Blood Bank via email tipe@uams.edu**.
4. **In the event of an emergency that is highly time-sensitive (response required is in less than 4 hours)** or where the provider is unable to complete and submit form 3926 due to extenuating circumstances, the provider may contact FDA's Office of Emergency Operations at **1-866-300-4374** to seek verbal authorization. If verbal authorization is given, the requestor must agree to submit form 3926 within 15 working days of FDA›s authorization of the use. **Please notify Dr. Tina Ipe immediately at tipe@uams.edu both at the time of verbal request and after the eIND number is obtained**.
5. In Epic, order "Convalescent Plasma (COVID-19)" [LAB3203]. You must enter the eIND number in the required field within the order.

The provision of convalescent plasma will be coordinated by ADH and UAMS once they have received the eIND number from the requesting physician. For Arkansas Blood Institute collected convalescent plasma units, these units will be available at their distribution facilities in Arkansas and will be provided upon receipt of the eIND number.

Tina Ipe, MD, MPH
Division Director, Transfusion Medicine
Ph: 501-603-1941
tipe@uams.edu

Ericka Olgaard, DO
Laboratory Director
Ph: 501-686-7444
ejolgaard@uams.edu