COVID-19 Convalescent Plasma Resources

- last updated APRIL 2, 2020

COVID-19 Convalescent Plasma Collection: Donor Eligibility, Processing, Labeling, and Distribution (last updated 03/31/20) CHANGES TO THIS PROTOCOL ARE IN PROGRESS BASED ON NEW INFORMATION FROM FDA – UPDATE WILL POST ON 04 03 2020.

- FDA has posted:
  - March 24, 2020 Investigational COVID-19 Convalescent Plasma - Emergency INDs
  - March 26, 2020 Investigational COVID-19 Convalescent Plasma - Emergency INDs Frequently Asked Questions

Overview

AABB joins the National Academies of Science, the National Academy of Engineering, and the National Academy of Medicine in calling for research into the use of convalescent plasma, a well-established technique that is showing promise in early studies with COVID-19 patients.

Although the indications are very preliminary at this stage, it appears that COVID-19 convalescent plasma (CCP) may be safe and may have the potential to reduce the duration and severity of COVID-19. Convalescent plasma treatment works because plasma collected from individuals who have already recovered from COVID-19, contains antibodies that could provide passive immunity, which may help patients fight the infection. Further investigation is still necessary to determine if convalescent plasma will shorten the duration of illness, reduce morbidity, or prevent death associated with COVID-19.

If this treatment is effective, a hyperimmune globulin pharmaceutical product will be the preferred delivery device for these antibodies. However, it could take several months to manufacture and produce this product. CCP will provide the bridge to future treatment with hyperimmune globulin - In the interim, blood centers and hospitals are partnering to collect convalescent plasma from patients who have recovered from COVID-19 to make this treatment widely available as quickly as possible.

FDA has posted these documents:

Investigational COVID-19 Convalescent Plasma - Emergency INDs – 03 24 2020

Investigational COVID-19 Convalescent Plasma - Emergency INDs Frequently Asked Questions – 03 26 2020

Key Points to Consider

- COVID-19 convalescent plasma (CCP) is currently being studied as a therapy for COVID patients; preliminary data from China suggest this is a promising bridge to the availability of a hyper immune globulin product.

- During this interim period, convalescent plasma from COVID-19 patients will be collected under a well-coordinated master protocol approved by FDA, to support administration of CCP under patient-specific emergency Investigational New Drug application (eIND) protocols, or under traditional FDA-approved INDs.
• The goal for the expedited regulatory approach would be broad commonality of practices related to CCP collection, labeling, and outcomes reporting, which is still expected to require a significant amount of coordination between hospitals and blood centers.

• For example, public health departments and hospitals will likely drive the identification and recruitment of recovered COVID patients to serve as CCP donors, but blood centers will be responsible for allogeneic donor qualification, collection and labeling, product safety, and distribution.

**ICCBBA Codes** for COVID-19 Convalescent Plasma

**Frequently Asked Questions**

**What is COVID-19 Convalescent Plasma (CCP)?**

CCP provides passive immune antibody therapy, with a track record of use dating back to the Spanish Influenza outbreak: [https://annals.org/aim/fullarticle/729754/meta-analysis-convalescent-blood-products-spanish-influenza-pneumonia-future-h5n1](https://annals.org/aim/fullarticle/729754/meta-analysis-convalescent-blood-products-spanish-influenza-pneumonia-future-h5n1)

The use of CP was evaluated as a possible tool during outbreaks of other influenza and respiratory illnesses (H5N1, H1N1, MERS-COV, SARS).

**Will it help the treatment of COVID patients?**

It appears that way – further investigation is still necessary. While we are a few months away from a possible pharmaceutical plasma product, blood centers and hospitals are partnering to produce CCP that could be used for COVID-19 patients under an FDA approved treatment protocol.

The use of convalescent plasma in the treatment of coronaviruses may be safe and effective. ([https://academic.oup.com/jid/article/211/1/80/799341](https://academic.oup.com/jid/article/211/1/80/799341)). Furthermore, early studies from China ([https://www.medrxiv.org/content/10.1101/2020.03.16.20036145v1](https://www.medrxiv.org/content/10.1101/2020.03.16.20036145v1)) suggest this may be ([https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30141-9/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30141-9/fulltext)) a promising option for management of COVID-19 patients, with the potential to reduce the severity and duration of illness in some patients.


**How Will Convalescent Plasma Be Collected?**

With support from FDA, AABB has a project underway to create a master collection protocol under which blood centers would be able to quickly implement uniform practices to expedite the availability of CCP. This master collection protocol will be different from the pathway [described by FDA](https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-inds) earlier this week because it will not be a patient-specific collection; rather, blood centers will collect and store plasma from convalesced individuals for use by hospitals under an FDA approved IND.

We expect the work on the master protocol to continue for a short time as we coordinate efforts to expedite FDA approval.

*Again – We remind you to check back often for updates on rapidly changing events and information.*