

To: Carter BloodCare Customers

From: Hospital Relations Department

Date: February 8, 2021

Re: UPDATE - COVID-19 Convalescent Plasma

Background

On February 4, 2021, the FDA revised the Letter of Authorization for COVID-19 convalescent plasma (CCP). The update restricts the use of *high titer COVID-19 CCP* to treatment of hospitalized patients with COVID-19 early in disease course, and to treatment of those hospitalized who have impaired humoral immunity and cannot produce an adequate antibody response.

Impact to Client

- Effective immediately, Carter BloodCare will only be distributing units qualified and labeled as high titer.
- The sole use of high titer CCP units will significantly reduce CCP availability. Maintaining a stock of high titer CCP at your facility will be based on current inventory levels.
- Low titer CCP units remaining in your inventory should be returned to Carter BloodCare following the normal return process. Requests for the return of low titer CCP will be treated as "routine."
- Updates to this process may be forthcoming as we continue to learn more from the FDA and other industry leaders.

Updated Fact Sheet for Patients and Parents/Caregivers can be found here: https://www.fda.gov/media/141479/download

Updated Fast Sheet for Health Care Providers can be found here: <u>https://www.fda.gov/media/141478/download</u>

A link to the February 4, 2021, update issued by the FDA is included for your reference <u>https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data</u>.