Carter BloodCare

To: Carter BloodCare Customers
From: Hospital Relations Department
Date: August 27, 2020
Re: UPDATE - Emergency Use Authorization for Convalescent Plasma

Background
Carter BloodCare participated in a joint meeting with ABC and the FDA yesterday, giving us the opportunity to learn new information regarding emergency use authorization (EUA) for emergency use of convalescent plasma. Please share the following details with your medical director and others as applicable.

- As of August 28, 2020 at 11:59 p.m. local time, the expanded access program (EAP) will no longer accept new patient enrollments. Until then, treating clinicians can still choose this pathway to request CCP for transfusion. For these CCP orders requested under the EAP, please continue to include patient name and EAP code on the fax order form.
- Additionally, clinicians can choose to transfuse under the EUA. CCP requested under the EUA does not require patient name or EAP code on the fax order form.
- The FDA is granting blood centers a transition period to make preparations for antibody titer testing and appropriate labeling under the EUA guidelines.
- Convalescent plasma previously collected and labeled as investigational use, can continue be used during the transition period to fill orders under the EUA.
- Convalescent plasma collected during the transition period can continue to be labeled for investigational use.
- The transfusion consent should be modified to include the EUA for convalescent plasma.
- Investigational use CCP units transfused under the EUA require transfusion recipient notification. Consent can be in the form of a documented verbal consent in the patient chart and/or written on the transfusion consent.
- The fact sheets (attached and @ https://iwebb.carterbloodcare.org/Memo/DownloadFile/4843 and https://iwebb.carterbloodcare.org/Memo/DownloadFile/4842) must be made available to the clinician and patient. Please ensure a mechanism is in place to make these fact sheets readily available. Fact sheets in Spanish are being prepared by the FDA and will be shared as they are made available.
- There will be new ISBT special testing codes for low and high titer convalescent plasma.
- At this time, there is no FDA guidance regarding dosing for pediatric use.
- The cost for convalescent plasma remains unchanged.