Carter BloodCare

To: Carter BloodCare Customers
From: Hospital Relations Department
Date: August 24, 2020
Re: Emergency Use Authorization for Convalescent Plasma

Background

As of March 27th, COVID-19 convalescent plasma (CCP) has been used in the management of COVID-19 through an emergency investigational new drug authorization. Many of you have obtained CCP under the National Convalescent Plasma Expanded Access Protocol (EAP). On August 23, 2020, the FDA issued emergency use authorization for emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with coronavirus disease (COVID-19). Please find attached the FDA's announcement and healthcare provider fact sheets. The FDA's decision memorandum can be found at https://www.fda.gov/media/141480/download.

Impact to Client

Please review the attached documents in preparation to request CCP under emergency use authorization.

As of today, August 24th, the Mayo Clinic EAP is discontinued for new patient enrollments; as a result, new patient CCP orders no longer require the EAP# on the fax order form. Eligible patients who were previously enrolled in the EAP can receive CCP and you can continue to order under the EAP#. The cost remains unchanged until new information regarding billing is made available.

We are developing plans to measure antibody titers, and until the plans are completed, we will not make any labeling changes. Additionally, CCP units collected prior to August 24th will not be re-labeled.

Please don't be surprised if we change our messaging because many of the issues with labeling and delivery of convalescent plasma may be modified as we gain a deeper understanding of the FDA's recommendations.