FDA Emergency Use Authorization for COVID-19 Convalescent Plasma
Copy of communication provided to Vitalant customers August 28, 2020

On Sunday, August 23, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for COVID-19 Convalescent Plasma (CCP) for the treatment of COVID-19 in hospitalized patients. Vitalant is working with the FDA, the Biomedical Advanced Research and Development Authority (BARDA) and our industry partners to understand the operational and financial implications of this change to both Vitalant and its hospital partners. While many questions remain, we want to share what we know now and will continue to update you as new information is available.

Can my hospital continue ordering CCP from Vitalant?
Yes. The FDA contemplates it will take the blood services industry several months to transition to the new manufacturing, testing, labeling and distribution standards set forth in the EUA. During the transition period, the FDA has advised that blood service providers to continue to manufacture, test, label and distribute CCP for investigational use in accordance with the same requirements prior to issuance of the EUA.

Under what pathway are hospitals authorized to administer CCP while the product is still considered for investigational use only?
Most hospitals have been ordering CCP for administration under the Expanded Access Program sponsored by the Mayo Clinic (the “Mayo EAP”). The Mayo EAP will discontinue new physician and new patient enrollments, effective Friday, August 28, 2020 at 11:59 p.m. EDT. Vitalant will continue to fulfill orders to support patients enrolled in the Mayo EAP through Monday, August 31, 2020 at 11:59 p.m. EDT.

Vitalant will also continue to fulfill CCP orders to support patients enrolled in traditional Investigational New Drug Applications (“IND”), which many of our hospital partners have sponsored or are serving as participating sites.

The FDA has informed the blood services industry that it will have a transition period for full compliance with the requirements set forth in the EUA, but that the blood service providers should continue to collect and ship under current requirements until the regulatory agency can provide further written guidance. Until this guidance is issued, the FDA has advised that health care practitioners can continue to administer CCP to hospitalized patients without the need for either a single emergency IND (eIND) or pursuant to an IND provided that the health care practitioners obtain informed consent from the patient or patient’s legally authorized representative due to the investigational status of the treatment. The FDA has exercised its enforcement discretion due to the pandemic circumstances in providing this pathway for administration to ensure that there is no disruption to treatment options of COVID-19 patients during this transitional period.

Is CCP still an investigational product?
Yes. Until blood service providers can operationalize the new manufacturing, testing, labeling and distribution requirements set forth in the EUA, health care practitioners should continue to administer CCP as an investigational product to hospitalized patients. As explained above, the FDA has exercised its enforcement discretion in providing this pathway for administration to hospitalized patients if the health care practitioner secures informed consent from the patient or the patient’s legally authorized representative to administer an investigational product.
Vitalant will continue to fulfill orders for CCP as investigational product pursuant to randomized, controlled studies under a separate IND for its hospital partners who are sponsoring or participating in clinical trials outside the context of the issuance of the EUA.

**Does administration of CCP require written informed consent if administered during this transitional period?**

Health care practitioners should continue to comply with the hospital’s policies and procedures governing informed consent until the FDA issues formal guidance on whether verbal or written informed consent will be required during this transitional period. Based on FDA’s preliminary guidance, Vitalant recommends health care practitioners administering CCP document that “investigational CCP” is being administered to the patient on the hospital’s standard informed consent form for blood transfusions or in accordance with the hospital’s policy governing informed consent in emergency circumstances. Health care practitioners should consult with the hospital’s Legal and/or Risk Management Departments with further questions regarding informed consent.

**Will billing for CCP change?**

Based on our conversations with the FDA and industry partners, Vitalant understand that BARDA will continue to reimburse the blood service providers for CCP units administered by health care practitioners during this transitional period. It is currently unknown when this will change. Vitalant will continue to invoice customers ordering CCP under separate IND studies and will seek BARDA reimbursement for units ordered under the Mayo EAP, eINDs and as investigational CCP through this transitional period until reimbursement for CCP is available directly to hospitals through Centers for Medicare and Medicaid Services (CMS) and other payors.

**When will Vitalant provide more information regarding the EUA transition?**

We expect more information on the EUA transition and impacts to Vitalant and its hospital partners in the coming days. We appreciate your patience in these unprecedented times. We plan to host an informational webinar to share additional information and answer your questions. Please put the following date and time on your calendar – we will send out detailed webinar information early next week. A recording will also be provided after the webinar if you are unable to attend.

**Vitalant Informational Webinar on EUA Transition**

Date: Wednesday, September 2
Time: Noon AZ/PDT (1 pm MDT/2 pm CDT/3 pm EDT)
Additional detail on registering for webinar to come.

Thank you for your ongoing partnership and collaboration. Please direct questions to your [local Vitalant contacts](mailto:local%20Vitalant%20contacts).