Frequently Asked Questions: EAP to EUA Transition

On August 23, 2020, the US Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19.

Is the discontinuation of the EAP effective immediately?

No, enrollment concludes on August 28 at 11:59pm EST, but physicians who have patients already enrolled in the EAP should continue to update and submit forms.

Can I still enroll patients in the Mayo Clinic Expanded Access Program (EAP)?

The Emergency Use Authorization (EUA) issued by the US FDA is currently active and going forward should be the preferred means of administering COVID-19 convalescent plasma. New patient enrollment in the Mayo Clinic EAP is not authorized after August 28, 2020.

Can I still transfuse patients with convalescent plasma under the Mayo Clinic Expanded Access Program?

The Emergency Use Authorization (EUA) issued by the US FDA is active and represents the preferred means of administering convalescent plasma. Placing an order for COVID-19 convalescent plasma under the Mayo Clinic EAP is not authorized after August 31, 2020.

What are the differences between the Expanded Access Program (EAP) and Emergency Use Authorization (EUA)?

Reference the EAP vs. EUA comparison information and the FDA Fact Sheet to learn more about the EUA.

How do I treat hospitalized patients with COVID-19 under the Emergency Use Authorization (EUA)?

Refer to the US FDA Fact sheet for health care providers for information on treating patients under the EUA.

Am I required to complete forms for patients enrolled on or before August 28, 2020?

Yes. It is a requirement of the EAP to complete the following forms for each patient enrolled in the EAP:

- Medical History Form
- Transfusion Forms
- Serious Adverse Event (SAE) Reports
- SAE Resolution Forms
- Weekly Patient Update/End of Study Forms
Where can I get more information and any fact sheets associated with the EUA?

- US FDA Fact sheet for health care providers
- US FDA press release