Convalescent Plasma Transition Plan – Effective 8/28

On August 23, 2020 the FDA issued an Emergency Use Authorization (EUA) for the administration of Convalescent Plasma (CP) to hospitalized patients who meet the criteria for treatment of COVID-19 under the EUA Scope of Authorization. The Mayo Clinic investigational study’s Expanded Access Program (EAP) was discontinued on August 28, 2020. The FDA EUA does not make provisions for those ministries that may have small stores of CP available for use, but not labeled in accordance with the new EUA. The following transitional plan may be utilized for interim to meet the needs of severely ill COVID-19 patients pending development of further FDA guidance.

What to do in the transition?

If the ministry has previously participated in the Mayo Clinic EAP Investigational Protocol:

<table>
<thead>
<tr>
<th>Providers</th>
<th>Transfusion Services/Blood Bank</th>
<th>Clinical Colleagues</th>
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</thead>
<tbody>
<tr>
<td>Continue to order Convalescent Plasma as patient needs dictate.</td>
<td>Dispense Convalescent Plasma, as available.</td>
<td>Administer the authorized COVID-19 convalescent plasma with antiSARS-CoV-2 antibodies according to standard hospital procedures and institutional medical and nursing practices.</td>
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<tr>
<td>Read the EUA Fact Sheet</td>
<td>Contact your blood supplier regarding best practices for ordering CP</td>
<td>Read the EUA Fact Sheet</td>
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<td>Dosage: 1 unit (200 ml)</td>
<td>Send the Fact Sheets (Provider and Patient) prior to the unit being delivered for transfusion.</td>
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<td>Amend or assure order for plasma unit to denote &quot;Convalescent Plasma for COVID-19&quot; in EHR</td>
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<td>Document administration of Convalescent Plasma in the patient’s EHR</td>
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<tr>
<td>Obtain and provide the patient a modified consent for administration of blood product that documents in the consent</td>
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and/or the patient’s EHR that includes the following language:

“You are receiving a non-EUA compliant unit of plasma that was manufactured under the prior Emergency Access Protocol (EAP)”

This can be written on the consent and/or be documented by the provider in the Electronic Health Record.

Give patient the EUA Fact Sheet (see modified fact sheet)

For ministries that have not participated in the Mayo Clinic EAP Investigational Protocol or other investigational protocol and not previously administered Convalescent Plasma the following MUST to be accomplished prior to order and administration of Convalescent Plasma:

1) Convene a team of appropriate ministry clinicians and colleagues to represent the key disciplines involved (Blood Bank, Laboratory Information Services, Clinicians, informatics, etc.) to identify needs and resources available to make CP available for patient care. The high-level actions / work needed include the following before ordering and administering CP:

✓ Assure order set for CP for treatment of COVID-19 is available and that providers are aware of how to order this blood product
✓ Ministry Blood Bank needs to contact their local community blood center to obtain the ISBT (International Society of Blood Transfusion) product codes of available CP products.
✓ Appropriate Codes (including charge codes) need to be built into both the electronic health record (EHR) system and LIS (e.g. ISBT product codes) for CP units received from the local blood products supplier at the ministry to allow providers to order and administer a unit(s) of CP
✓ Use existing patient consent for receipt of blood products or documented in the patient's EHR, however the following is required language that needs to be added prior to the patient consideration and signature of acceptance:

You are receiving a non-EUA compliant unit of plasma that was manufactured under the prior Emergency Access Protocol (EAP)

✓ If administering COVID-19 convalescent plasma track serious adverse events that are considered to be potentially attributable to COVID-19 convalescent plasma use and report these to FDA in accordance with the Fact Sheet for Health Care Providers.

This guidance will be updated as additional information from the FDA becomes available.

References:


FDA. EUA Fact Sheet for Patients and Parents/Caregivers. 8/23/2020