VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*6/9/2020*
Last Approved:	*6/9/2020*
Last Revised:	*6/9/2020*
Next Review:	*6/9/2023*
Owner:	*Jason Arimura: Director-Pharmacy Services*
Policy Area:	*COVID-19*
References:	

Convalescent Plasma as Exploratory Treatment for COVID-19

POLICY

I. **Clinical Background**

A. Coronavirus disease-19 (COVID-19) is a serious infection with a high risk of pulmonary failure and death, particularly in elderly patients. California has an epidemic in 2020 that is likely to persist. Clinically severity is widely disparate from asymptomatic infections, a mild catarrh to fulminant respiratory failure.

B. Availability of anti-viral directed treatments is limited. Current management centers on respiratory care and control of comorbid illnesses, until patient recovery or death.

C. August 23, 2020 the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) has stated, "COVID-19 convalescent plasma [CCP] is human plasma collected from individuals whose plasma contains anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. It is an investigational product and is not currently approved or licensed for any indication. Based on review of historical evidence using convalescent plasma in prior outbreaks of respiratory viruses, certain preclinical evidence, results from small clinical trials of convalescent plasma conducted during the current outbreak, and data obtained from the ongoing National Convalescent Plasma Expanded Access Protocol (EAP.

D. **Exploratory Treatment**

A. The FDA had authorized an expanded access program (EAP) for CCP as an Investigational New Drug (IND). The program is managed by Mayo Clinic. The investigators released a pre-print paper on 35,000 hospitalized patients. Fifty-two percent were in intensive care. The seven-day mortality was 8.7-11% Thirty-day mortality ranged from 21.6% for early treatment to 26.7% for later treatment.

B. Vitalant Blood Services, the provider of blood products for Ventura County Health Care Agency (VCHCA), has a CCP donor program available to hospitals under the EUA.

C. Without available treatments for high morbidity disease, the exploratory use of CCP for consenting adult patients is a reasonable approach. The EUA offers a readily accessible process to treat with CCP.

Treating physicians may still choose to use CCP under an Investigational New Drug. That process is governed by Policy 100.035 (Investigational Drugs and Devices), and PH.40 (Investigational Drug Use).

PROCEDURE

I. **Candidate Patients**

A. Patients 18 years and older with lab confirmed Severe Acute Respiratory Syndrome associated Coronavirus-2 (SARS-CoV2) disease are eligible.

B. Either severe or life-threatening disease, or high risk for same.

1. Life threatening disease defined as respiratory failure, multi-organ dysfunction or septic shock.
2. Severe disease defined as either dyspnea, respiratory frequency >30 breaths/minute, blood oxygen saturation <93%, lung infiltrates >50% within 48 hours, or partial pressure of arterial oxygen to fraction of inspired oxygen ratio <300.
3. Judged by the provider at high risk to progression to severe or life-threatening disease.

II. **Informed Consent**

A. All patients or their healthcare proxy will undergo and sign an informed consent.

1. Option 1: Obtain written informed consent from the patient. If the doctor or designee cannot enter the room, the consent process can occur via telemedicine device or telephone, and a photograph of the written signed informed consent can be returned electronically.
2. Option 2: Use a legally authorized representative to sign an informed consent document if the patient is unable to provide consent because of an impairment or unable to communicate.
3. Option 3: In an emergency, informed consent can be exempted/implied. Two physicians must concur with the participation in the program for convalescent plasma. The treating physician must document the indications for program enrollment and the reason for lack of informed consent. The second physician must place a note in the medical record concurring with the patient's participation. The physician must update the patient (or their proxy) as time progresses.
4. The patient and/or healthcare proxy shall receive the Convalescent Plasma Fact Sheet for Patients and Caregivers in appropriate language.

III. **Ordering Convalescent Plasma**

A. Blood type: an active blood type within the last 7 days has been completed.

1. ABO compatible convalescent plasma will be transfused.

Patient Blood Type	A	B	AB	O
Compatible Plasma	A, AB	B, AB	AB	A, B, O, AB

B. Contact Blood Bank and Vitalant. Ensure prescriber has read and understands the "Convalescent Plasma EUA Fact Sheet for Health Care Providers"

C. Order a transfusion of "COVID Convalescent Plasma Most patients will tolerate 250 mL/hr. Use a slower rate in volume sensitive patients.

D. Order premedication of acetaminophen and diphenhydramine as warranted.

IV. **Dosing & Administration**

A. Plasma may be obtained from volunteer orders by apheresis for standard whole unit.

B. The dose is, therefore, 200 mL to 500 mL of ABO compatible convalescent plasma over 1 to 2 hours

(at 100 to 250 mL/hr). Nursing shall follow MST.18 Blood and Blood Component Transfusion for administration and documentation of CCP transfusion.

C. Record and report any transfusion reactions.

V. **Record Keeping**

A. The FDA requires, "All descriptive printed matter, including advertising and promotional material, relating to the use of COVI D-19 convalescent plasma clearly and conspicuously shall state that:

1. •COVI D-19 convalescent plasma has not been approved or licensed by FDA; •COVID-19 convalescent plasma has been authorized by FDA under an EUA; •COVI D-19 convalescent plasma is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVI D-19 pandemic under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner."

B. Serious adverse events (SAE) related to convalescent plasma are recorded in the medical record and reported to Blood Bank for review in Blood Committee.

1. SAE include death, disability, life threatening conditions, need for surgery, insertion of device(s), or prolonged hospitalization.
2. Clinician assessment of CCP causality of SAE is documented in electronic medical record (definite, probable, not probable, not related)
3. For example, TRALI after infusion is a life-threatening event and is caused by the plasma infusion. COVID-19 pneumonia and death are not related to CCP.

C. Concomitant medications

Other exploratory, emergency use and investigational agents are allowed and shall be documented in the medical record

Resources

Rajendran, K, Krishnasamy, N, Rangarajan, J, Rathinam, J, Natarajan, M, Ramachandran, A. Convalescent plasma transfusion for the treatment of COVID-19: Systematic review. *J Med Virol*. 2020; 1– 9. https://doi.org/10.1002/jmv.25961

Early Safety Indicators of COVID-19 Convalescent Plasma in 5,000 Patients. Joyner. doi: https://doi.org/10.1101/2020.05.12.20099879

All revision dates: 6/9/2020

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
PolicyStat Administrator	Jason Arimura: Director-Pharmacy Services	6/9/2020
Policy Owner	Jason Arimura: Director-Pharmacy Services	6/9/2020