



TITLE	Convalescent Plasma Administration		
TODAY'S DATE	July 16, 2020		
SECTION	<input type="checkbox"/> Organization Wide	<input type="checkbox"/> PPE	<input type="checkbox"/> OB/GYN
	<input type="checkbox"/> Emergency Department	<input type="checkbox"/> Surgery	
	<input checked="" type="checkbox"/> Inpatient	<input type="checkbox"/> Ambulatory	
	<input type="checkbox"/> Nursing	<input type="checkbox"/> Medical staff [physicians and advance care practitioners]	

APPLICABLE LOCATIONS	<input type="checkbox"/> All Bozeman Health locations <input checked="" type="checkbox"/> Bozeman Health Deaconess Hospital <input type="checkbox"/> Big Sky Medical Center	<input type="checkbox"/> Belgrade Clinic + UrgentCare <input type="checkbox"/> Hillcrest Senior Living <input type="checkbox"/> b2 UrgentCare <input type="checkbox"/> b2 MicroCare
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APPROVAL DATE	July 19, 2020

PURPOSE:

To provide guidance on eligibility and process for convalescent plasma administration during COVID-19.

POLICY/PROTOCOL:

PATIENT ELIGIBILITY

Inclusion Criteria

1. Age at least 18 years
2. Laboratory confirmed diagnosis of infection with SARS-CoV-2
3. Admitted to an acute care facility for the treatment of COVID-19 complications
4. Severe or life threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease
5. Informed consent provided by the patient or healthcare proxy

***If a patient is less than 18 years of age, the physician must work with the laboratory medical director to obtain an FDA single patient Emergency IND.**

Severe COVID-19 is defined by one or more of the following:

- Dyspnea
- Respiratory frequency ≥ 30 /min
- Blood oxygen saturation $\leq 93\%$
- Partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300
- Lung infiltrates $> 50\%$ within 24 to 48 hours

Life-threatening COVID-19 is defined as one or more of the following:

- Respiratory failure
- Septic shock
- Multiple organ dysfunction or failure

PROCEDURE**Approval**

Pulmonology/Critical care physicians and Hospitalists will be the ordering physicians. Blood bank will call the Pathologist on call to approve the use of COVID-19 convalescent plasma before dispensing.

Ordering

COVID-19 Convalescent plasma will be ordered in EPIC as FFP in units. Physician must put COVID-19 Convalescent plasma in ordering comments. Physician must call the blood bank to make sure we have ABO compatible plasma in stock as well as communicate the need to the blood banker. Dosing is typically one or two units that are approximately 200 ml each.

Blood bank testing

A banded type and screen must be completed before plasma is assigned to patient. Plasma will then be thawed and assigned in HCLL (blood bank software) as FFP using the FFP2 (FFP in units) product fulfillment bar.

***COVID-19 convalescent plasma will not be tubed in the tube system due to the specialty of the blood product.**

Plasma administration

COVID-19 convalescent plasma is administered the same as FFP and must be documented in EPIC using BPAM by the RN.

Documentation

Ordering physician must fill out FDA/Mayo Clinic documentation:

1. Physician must go the following website and register as a PI and complete the patient enrollment form.
<https://www.uscovidplasma.org/physicians>
2. Patient consent must be signed and kept in the hospital medical record.
3. 4 hours post –transfusion documentation
https://redcap2.mayo.edu/redcap/surveys/?s=X78R9TDHT&_ga=2.196042220.1596401270.1588778105-492101804.1588435202
4. 7 day post –transfusion documentation
https://redcap2.mayo.edu/redcap/surveys/?s=CX3EJTLH4T&_ga=2.158740858.1596401270.1588778105-492101804.1588435202
5. If patient is still hospitalized at 30 days, 30 day post transfusion documentation must be completed.
- 6.

NOTES:

Because COVID-19 convalescent plasma (CCP) has not yet been approved for use by FDA, it is regulated as an investigational product. Bozeman Health has joined Mayo Clinic's investigational expanded access protocol.

Convalescent plasma has appeared to be of benefit for the treatment of certain infectious diseases, including infections from respiratory viruses. Preliminary evidence indicates that convalescent plasma may be of benefit to some patients with COVID-19, leading to improvement of symptoms.

One of the ways that people fight infectious diseases is by developing antibodies that lead to the destruction of the invading microorganism. The antibodies are present in the blood, and more specifically, in the liquid portion of the blood called plasma. People who have recovered from being recently infected can donate plasma and that plasma can then be given to individuals who are ill with the virus in order to try to help eliminate it and allow them to improve clinically. This has worked in previous outbreaks of respiratory diseases like influenza, and there are some early data to suggest that it might work for some people with COVID-19.



- FDA: Recommendations for Investigational COVID-19 Convalescent Plasma.
- Mayo Clinic: Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19.

OTHER POLICIES/PROTOCOLS TO REFERENCE:

SCOPE:

We anticipate these adjustment to be temporary and reserve the right to revise or discontinue these adjustments with or without notice depending on the current understanding and/or business needs of Bozeman Health relating to COVID-19.