

Current Status: Pending PolicyStat ID: 8391376



Origination: 4/28/2020 Effective: Upon Approval Final Approved: N/A Last Revised: 8/13/2020 Next Review: 2 years after approval

Owner: Irene Wittkop: Coord,

Transfusion Service

Policy Area: Lab - Transfusion Service

References:

Applicability: Sutter Roseville Medical Center

Managing Covid Convalescent Plasma Orders

Managing COVID-19 Convalescent Plasma Orders

Purpose Provide instruction for the management of COVID-19 Convalescent Plasma (CCP) orders once the Transfusion Service is notified by a provider of a patient need.

Policy

- Plasma will be tagged by the blood supplier as investigational.
- · Units will only be used for COVID-19 patients who have been assigned an IND (Investigational New Drug) number after having been enrolled in an EAP by a licensed provider.
- Transfusion Services will be responsible for distributing the COVID-19 Convalescent Plasma Order form.
- · Plasma should not be ordered and/or thawed until completed form Convalescent Plasma Order form and evidence of signed MAYO Clinic Consent form is received and reviewed by the Transfusion Services Dept.
- Each IND number covers the patient for up to 2 transfusions of CCP. Each CCP unit is approximately 200 mL.
- · COVID-19 Convalescent Plasma will only be ordered for patients over 18 years old with severe or life-threatening COVID-19 disease.
- · In the event a physician would like to transfuse a pediatric patient, they will need to work directly with the Mayo Clinic EAP team.
- Use of ABO incompatible convalescent plasma, as needed, has been granted by the Laboratory Medical Director with the approval of the ordering physician. Document physician approval for incompatible product using a BBC in SQ.

EPIC Ordering

The ordering provider will place an order in EPIC for "COVID Convalescent Plasma" and notify Transfusion Services.

Plasma Order Form

Once verbal or EPIC order is received perform the following:

Step	Action
1	Label a copy of the COVID-19 Convalescent Plasma Order Form with an EPIC label and complete the top portion of the form.
2	Provide the Ordering Provider, or an assigned representative with the COVID-19 Convalescent Plasma Order Form from step 1.
3	Inform the Provider or care team member that the completed Order form and evidence of signed MAYO Convalescent plasma consent form must be received by the Transfusion Services before product will be ordered from the supplier.

Consent

ep Action			
Verify a signed Mayo consent form has been obtained.			
If confirmed by		Then	
Viewing in EPIC media tab		 Select chart review tab. Select media tab. Open consent form from Mayo clinic. Proceed to step 2.	
Requesting copy of the consent from the floor		Proceed to step 2.	
Verify the form has completed signature blocks for the patient/representative and the physician. If: Then:			
Both signature blocks are complete	Proceed to step3.		
	Verify a signed Mayo collification of the Verify the form has coming the Both signature blocks	Verify a signed Mayo consent form has been obtained by Viewing in EPIC media tab Requesting copy of the consent from the floor Verify the form has completed signature blocks for the image. Then: Both signature blocks Proceed to step3.	

	If:	Then:
	Floor agrees to complete	Proceed to step 3.
	Floor will not complete	 Notify them the product cannot be ordered until consent is complete with signatures. Notify the affiliate Research contact. NOTE: Notify them the following work day if after hours and no answer.

Processing an Order for the Plasma Product

DO NOT place an order for plasma until the order form is returned with a Mayo patient ID number documented on it, and there is a completed consent.

Step	Action			
1	Verify patient has an ABO type on record. If not, type patient immediately.			
2	Determine the product availability .			
	If there is	Then		
	Type compatible unit in storage at affiliate	Proceed to affiliate appropriate SOP for thawing the product		
	No type compatible unit in storage at the affiliate.	Place an order for the convalescent plasma in the Vitalant on line customer portal. Select "COVID-19 Convalescent Plasma" from the modifiers list associated with plasma. Indicate in the comments section that it is for immediate patient need TAT on order can be 1-3 days, if no stock available, especially if type compatible product is needed.		
	No product is available from Vitalant within time frame needed for patient	Contact ARC to request COVID Convalescent plasma Call 1-800-564-1947 () () () () () () () () () (
3 Mark the Ordered box on the Convalescent Plasma Order form when product has been				

Receiving a Convalescent Plasma

Enter plasma into SQ inventory system once Convalescent Plasma is received at the affiliate.

- Unit will arrive with a tie tag designating it as a "Convalescent Plasma".
- The product code will designate it as a "Convalescent Plasma".
- · All bags collected for a designated affiliate will be sent to directly from the blood supplier to that affiliate.
- Whenever possible, frozen convalescent plasma should be segregated from other FFP inventory.

Preparing Product Order

Follow the steps below to prepare the product.

	Step	Action	
	1	Ensure you have a EPIC Convalescent order for the patient, along with completed COVID-19 Convalescent Plasma Order form and evidence of signed MAYO consent form.	
	2	Thaw plasma according to affiliate specific SOP.	
3 Perform component preparation using the processing codes listed in the "Component Prep			

	and Labeling Table" section below.
	NOTE: The expiration date of 5 days will display and print out label.
4	Line out the following statement on the product label, "See tie tag for antibody titer levels". • Affix label to the unit.
5	Allocate product to the patient according to affiliate specific SOP.
6	Notify the floor when the product is ready for pick up.
7	Provide a copy of the nursing job aid titled "Investigational COVID-19 Convalescent Plasma" with each unit issued to the floor, if nursing requests administration support.
8	Add the Issued Date to the appropriate space on the Convalescent Order form.

Finalizing Paperwork

Once unit has been issued to the patient, place the paperwork in the Transfusion Service Specialist/Supervisor mailbox for scanning into EPIC. The Transfusion Service Specialist or their designee will scan the COVID-19 Convalescent Plasma Order Form into EPIC as follows:

- Sign into EPIC and select media manager tab, click on order option
- · Select the plasma order associated with the convalescent plasma
- · Scan the document
- · Review the scan to verify it scanned appropriately
- · Select "Lab Test Result" from the Document Type drop down
- Free text "CCP Order" in the Document Description

Update the Patient Listing spread sheet and Email Stacy Ralston as notification of the order. Save electronic or paper copy and store according to regulatory requirements.

Transfusion Reaction

In the event the patient experiences any signs and/or symptoms of a transfusion reaction follow dept. specific SOPs for managing, reviewing and reporting them

Component Prep Code and Labeling Table

Input E Code	Component Prep Function Code	SQ Code	5 Day Output Code
E9747V (Vitalant code)	C9747	E9752V	CVFPT
E9754V (ARC code)	C9754	E9562V	CFFP1T
E9755V (ARC code)	C9755	E9763V	CFFP2T
E9756V (ARC code)	C9756	E9756V	CFFP3T

All revision dates: 8/13/2020, 4/28/2020

Attachments

CCP Primary Contact Info Convalescent Plasma Order Form COVID 19 Convalescent Plasma Nursing Job Aide

Approval Signatures

Step Description	Approver	Date
Laboratory Director	Lindsey Westerbeck: Dir, Lab	pending