

CCP Information for Hospital Blood Banks

Last Updated: May 08, 2020

LifeServe CCP Collection Product Codes:

(Updated 5/08/2020)

E9747 = Apheresis CONVALESCENT PLASMA|ACD-A/XX/<=-18C|COVID-19

E9747A0

E9747B0

E9747C0

E9747D0

For thawed units of E9747 at your facility, see ICCBBA codes below:

E9752 = Thawed Apheresis CONVALESCENT PLASMA | ACD-A/XX/refg | COVID-19

E9752A0

E9752B0

E9752C0

E9752D0

E9753 Apheresis CONVALESCENT PLASMA | ACD-A/XX/<=-18C | Irradiated | COVID-19

E9753A0

E9753B0

E9753C0

E9753D0

E9766 Apheresis CONVALESCENT PLASMA | NS/XX/<=-18C | COVID-19

E9766A0

E9766B0

E9766C0

E9766D0

For thawed units of E9766 at your facility, see ICCBBA codes below:

E9782 Thawed Apheresis CONVALESCENT PLASMA|NS/XX/refg|COVID-19

E9782A0

E9782B0

E9782C0

E9782D0

E9735 CONVALESCENT PLASMA | CPD/XX/<=-18C | COVID-19 E9749 CONVALESCENT PLASMA | NS/XX/Frozen | COVID-19

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E9754 Apheresis CONVALESCENT PLASMA | ACD-A/XX/<=-18C | COVID-19 | 1st Container E9755 Apheresis CONVALESCENT PLASMA | ACD-A/XX/<=-18C | COVID-19 | 2nd Container E9756 Apheresis CONVALESCENT PLASMA | ACD-A/XX/<=-18C | COVID-19 | 3rd Container E9757 Apheresis CONVALESCENT PLASMA | ACD-A/XX/<=-18C | COVID-19 | 4th Container

E9748 Apheresis CONVALESCENT PLASMA | NS/XX/Frozen | COVID-19

E9748A0

E9748B0

E9748C0

E9748D0

Additional CCP Product Codes Available Nationally:

(*Updated 2/11/2021*)

Additional CCP product codes are available nationally and are available for use by other facilities. Although additional codes are not utilized by LifeServe Blood Center, in the event that we must import a unit, we can't control what codes other centers use. It is important to note, that nationally the newest codes are in the EA format. It may be a benefit to your team to review your process for how to bring in a unit if the product code is not established in you system.

Convalescent Plasma Product Appearance upon Arrival at Your Facility: (Updated 4/03/2020)

We will provide a visual cue outside of the product code to alert your staff that the product you are receiving is a CCP product. We will pack CCP products in a pink bubble wrap pouch. These are not intended as a replacement product for patients receiving our standard transfusable plasma products. CCP products are a high value plasma product intended as an Emergency Investigational New Drug for COVID-19 patients. These units will also include the following statements:

- Collected from a donor with pre-existing antibodies to SARS-CoV-2
- Caution: NEW DRUG LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE

Emergency Use Authorization and Fact Sheet:

(Updated 2/12/2021)

The label does reference the circular of information. The FDA does recognizes that the current circular of information does not contain specific information about COVID-19 convalescent plasma regarding indications for use, dosage information, contraindications or cautions, but it does provide information on the use of plasma. Additionally, **Fact sheets are available and were updated on February 4th, 2021.** I am including updated copies with this communication, but they can also be found linked below. Please share these appropriately at your hospital to make them available to healthcare providers, patients, and caregivers, respectively.

- Letter of Authorization
- Fact Sheet for Health Care Providers
- Fact Sheet for Patients and Parents/Caregivers

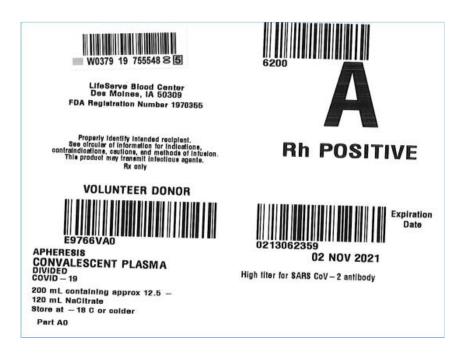
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Emergency Use Authorization / High Titer anti-SARS-CoV-2 antibodies: (Updated 2/12/2021)

LifeServe will begin providing High-Titer COVID-19 Convalescent Plasma (CCP) units starting Monday, February 15th, 2021. Our products will continue to be qualified utilizing two antibody testing platforms, one of which will provide the titer result. Moving forward, all CCP donors must qualify as high titer to meet the criteria to manufacture as CCP units.

Our CCP product codes will remain unchanged. LifeServe will continue to utilize our existing product codes. The product label will include the High-Titer designation in the lower, right quadrant stating, "High titer for SARS CoV-2 antibody". I have attached with this communication sample labels for each product code collected by LifeServe with the visual of the High-Titer statement. We are actively coordinating with the testing facility to procure titer results on units CURRENTLY in inventory. For inventory units that now qualify as high-titer, the "High titer for SARS CoV-2 antibody" statement will be added to the existing tie tag attached to the unit.

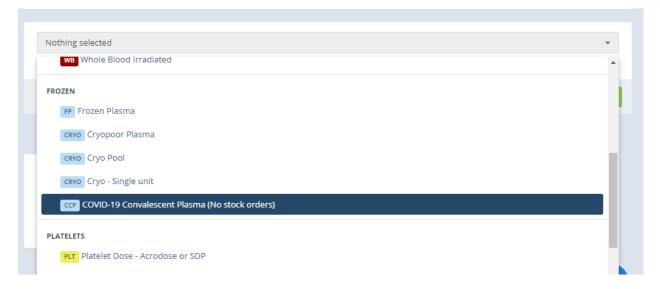


Utilizing BloodHub for Online CCP Ordering:

(Updated 8/25/2020)

Starting Monday, August 24th, 2020, COVID-19 Convalescent Plasma will be now be available to all hospitals as a Standard Order Type through the FDA's Emergency Release Authorization. Please note, although CCP will be orderable as a standard order, this is not an item that may be ordered for inventory purposes. These will continue to be distributed as patients have orders to transfuse CCP.





Billing: (Updated 8/25/2020)

Billing and/or reimbursement for convalescent plasma distributed under the FDA's Emergency Use Authorization has not yet been made available. I will share information on billing and/or continued reimbursement by BARDA once that information is established. At this time, LifeServe will continue to dispense CCP products to your hospital at no cost.

Reporting Final Disposition of CCP Units

(Updated 07/28/2020)

With the most recent update to the criteria for reimbursement of CCP units, reports of the unit's final disposition is expanding. Please continue to report CCP transfusions via BloodHub or emailing unit information to DailyTransfusions@lifeservebloodcenter.org. Additionally, LifeServe now requires you to report discarded units that have broken during the thawing process. If you need a replacement unit sent, please submit a new CCP service order and enter a comment with the unit number/product code stating that it broke during thawing. Please also notify <u>DailyTransfusions@lifeservebloodcenter.org</u> of the broken unit# and product code for our records.

For traceability, please notify LifeServe if you have received a CCP unit, but your orders to transfuse are subsequently canceled. We will evaluate based on type and usage to facilitate a return as needed.

Procedure Codes for COVID-19 Convalescent Plasma

(Updated 07/31/2020)

CMS released new procedure codes for COVID-19 convalescent plasma, which will allow Medicare and other insurers to identify the use of CCP for treating hospital inpatients with COVID-19. These new codes go into effect on August 1.

Procedure Code	Description		

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XW13325	Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW14325	Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5

Returned Units from COVID-19 Patient Rooms

(Updated 04/09/2020)

Listed below is additional information regarding units returned to your Blood Bank from a confirmed COVID-19 patient room or from a Person Under Investigation (PUI) for COVID-19 after the transfusion has been canceled. We realize that there are other potential infectious agents present in many patient's rooms. With the current heightened situation of the COVID-19 pandemic, the concern is only in regards to units returned with exposure to this particular virus.

- This should not be a common occurrence. We strongly suggest not issuing a unit unless there are orders for transfusion and the patient has been prepared to receive the unit immediately after the unit has been issued.
- Blood bags are porous and permeable to oxygen allowing excellent preservation of blood components. This means disinfectants CANNOT be used on the exterior of blood bags.
- If a unit is returned from a PUI patient room and their COVID-19 testing is still pending, please quarantine the unit via your internal process. If COVID testing results negative, this unit can return to general inventory, assuming all other return criteria were met.
- In an overabundance of caution, LifeServe CANNOT accept products back once they enter a patient room who has tested positive from COVID-19. These would need to be discarded at your facility as there is no way to disinfect the bag. Units discarded after returning from a COVID-19 room will NOT be credited by LifeServe.
- You may develop a protocol or policy with your infection control team specific to your facility to ensure exposure to virus can be prevented upon entry to a COVID-19 patient room to salvage the unit in the event it is returned. This would need to be reviewed and approved by our Quality Department before we can accept the returned product.