



Advancing Transfusion and  
Cellular Therapies Worldwide



American  
Red Cross

May 5, 2020

James Berger  
Designated Federal Officer  
Office of Infectious Disease and HIV/AIDS Policy  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

**Re: Request for Funding from HHS for COVID-19 Convalescent Plasma Collection Reimbursement**

Dear Mr. Berger:

AABB, America’s Blood Centers and the American Red Cross are requesting funding to pay for COVID-19 convalescent plasma (CCP) that is not otherwise reimbursed. Our organizations - which collectively represent the nation’s blood collection establishments, transfusion services, and transfusion medicine professionals - are working hard to collect and deliver CCP to patients recovering from COVID-19 during this public health emergency.

The Food and Drug Administration (FDA) is making CCP widely available to patients with COVID-19 through three investigational pathways: (1) an expanded access protocol (EAP), which is being led by Mayo Clinic; (2) a Single Patient Emergency Investigational New Drug (eIND); or (3) other clinical trials. As explained in more detail under the executive summary, there are no current reimbursement pathways for CCP to be reimbursed outside of BARDA grants awarded to America’s Blood Centers and the American Red Cross. Thus, hospitals and patients will need to absorb these costs.

We respectfully submit this request for funding to establish a payment mechanism for CCP furnished to all patients, including patients who receive CCP under eIND, clinical trials, or the EAP (if not covered by BARDA) so that the neither the patients, blood centers or hospitals will be required to absorb the cost of the treatment.

If you have any questions or need additional information, please contact Leah Stone at [lmstone@aabb.org](mailto:lmstone@aabb.org) or 301-215-6554.

Sincerely,

Debra BenAvram  
Chief Executive Officer  
AABB

Kate Fry  
Chief Executive Officer  
America’s Blood Centers

J. Chris Hrouda  
President, Biomedical Services  
American Red Cross



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## I. Request

We request that HHS consider two options for this funding request.

- **Option 1:** Our preferred approach would be for the Department of Health and Human Services (HHS), BARDA and Center for Medicare and Medicaid Innovation (CMMI) to enter into an interagency agreement to provide hospitals with funding to cover the costs of CCP. CMMI would use CMS' existing infrastructure to receive claims from hospitals for CCP that is furnished under one of the investigational pathways and which is not otherwise reimbursed, and to reimburse the hospitals based on their costs incurred.
- **Option 2:** Alternatively, we request that a cooperative agreement be awarded for the administration of the funds.

### 1. **Total Annual Budget requested**

**Option 1:** 22,493 units \* \$750 = **\$16,869,750**

**Option 2:** Option 1 + administration costs

America's Blood Centers and the American Red Cross agreed to a reimbursement rate of \$750/unit of CCP in their contracts with BARDA. The estimates included in this proposal are based on this reimbursement rate. In contrast, blood centers and hospitals entered into private contracts for CCP furnished outside of the EAP, and we are uncertain whether blood centers are charging hospitals the same price for CCP furnished under these contracts.

### 2. **Action Status: # of years planned**

We are requesting 1 year of funding beginning retroactively from March 13, 2020 (start of HHS Public Health Emergency) to be disbursed to hospitals collecting CCP.

### 3. **Mechanism – Are you proposing a Contract/Cooperative Agreement/Grant/ IAA-CSA/IDDA?**

- Option 1 (preferred approach):** We request for the funds to be administered through an IAA-CSA between the Department of Health and Human Services (HHS), BARDA and CMS' Center for Medicare and Medicaid Innovation (CMMI).
- Option 2:** Cooperative Agreement

### 4. **Expected Deliverables / Outcomes: Briefly describe expected deliverables / outcomes.**

The Federal government did not want reimbursement to be a barrier for CCP. Thus, BARDA entered into contracts with America's Blood Centers and the American Red Cross to cover the cost of CCP furnished under the EAP. However, this arrangement does not cover the cost of CCP furnished to all patients. Similarly, the Federal government has changed reimbursement policies applicable to tests and treatments related to COVID-19. This funding request is consistent with other efforts by ensuring that patients,



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blood centers and hospitals are not required to absorb the cost of CCP, regardless of the investigational pathway under which CCP is furnished.

##### **5. Executive Summary: Briefly describe initiative and provide strong justification.**

Since COVID-19 convalescent plasma (CCP) has not yet been approved for use by the Food and Drug Administration (FDA)<sup>1</sup>, it is regulated as an investigational product. The FDA is making CCP widely available to patients with COVID-19 through three investigational pathways: (1) an [expanded access protocol](#) (EAP), which is being led by Mayo Clinic; (2) a [Single Patient Emergency Investigational New Drug](#) (eIND); or (3) other clinical trials.

Hospitals and clinicians throughout the country view CCP as a promising investigational therapy and are accessing it through one or a combination of a few of these pathways. As of May 5, 2020, 10,070 patients are enrolled in the Mayo EAP and 5,416 units of CCP have been transfused under this pathway. Additionally, many hospitals have shared that they are providing CCP to patients under eINDs; it is our understanding that some hospitals will exclusively provide CCP under the eIND pathway while others will be using a combination of the three pathways. In addition, some hospitals will be enrolling qualified patients under different clinical trials.

The Federal government does not want reimbursement to be a barrier to access for CCP. Thus, the Biomedical Advanced Research and Development Authority (BARDA) entered into contracts with America's Blood Centers and the American Red Cross to pay for the CCP that is furnished to patients through the EAP. As a result of the BARDA funding, neither hospitals nor patients will be charged for the CCP furnished under the EAP.

However, there is no reimbursement pathway for CCP outside of the BARDA contracts. Hospitals have shared concern and confusion related to payments for CCP provided to patients under eIND or other clinical trials. Additionally, we are uncertain whether the BARDA contracts will be sufficient to fund all CCP furnished under the EAP.

AABB reached out to the Centers for Medicare and Medicaid Services (CMS) to get clarification on reimbursement of CCP under current Medicare rules. CMS responded that only routine medical costs for testing and treatment are covered. Specifically, Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the National Coverage Determination (NCD) process.<sup>2</sup> Thus, Medicare will not cover the costs of CCP collected and furnished to patients under any of the investigational pathways.

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<sup>1</sup> Convalescent plasma is a biological product subject to licensure under section 351 of the PHS Act. 42 U.S.C. 262(a).

<sup>2</sup> CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

(<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true>)