January 14, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Ms. Brooks-LaSure:

The Association for the Advancement of Blood and Biotherapies (AABB), America's Blood Centers and the American Red Cross, which collectively represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals, request that the Centers for Medicare & Medicaid Services (CMS) expeditiously update its coverage and reimbursement policies for COVID-19 convalescent plasma (CCP) to ensure that patients have access to CCP furnished in both the outpatient and inpatient settings of care, as permitted under the recently revised Emergency Use Authorization (EUA).

On December 28, 2021, the Food and Drug Administration (FDA) issued a revised EUA for CCP that authorizes "the use of the authorized COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies for treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or inpatient setting."[1]

However, CMS' current billing and reimbursement policies for CCP only apply to the hospital inpatient setting. In an interim final rule published on November 6, 2020, CMS established the following two ICD-10-PCS procedure codes for the transfusion of COVID-19 CCP:

- 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)

At the time that the interim final rule was published, the EUA only applied to patients receiving CCP in the hospital inpatient setting of care. In the preamble to the interim final rule, CMS recognized that the Agency would need to create new codes for CCP administered in the outpatient setting once permitted by FDA:

> ….Because treatment of COVID–19 is rapidly evolving, we believe it is important to ensure that separate payment is available under the OPPS for new drug and biological products (including blood products) that receive an EUA for treating COVID– 19 in the outpatient setting or are approved by the FDA for treating COVID–19 in the outpatient setting, or where a drug or biological product approved under an existing EUA is authorized for use in settings other than the inpatient setting. As part of that process, we expect to include the addition of new codes

[1] U.S. Food and Drug Administration, Convalescent Plasma EUA Letter of Authorization, December 28, 2021, *available at* https://www.fda.gov/media/141477/download.

describing those treatments as soon as practicable, after their availability, to ensure efficient and timely beneficiary access to those treatments. We anticipate that most drugs and biological products authorized for use in treating COVID–19 in the outpatient setting would be separately paid under our standard OPPS payment policy because drugs and biological products are typically assigned separate Ambulatory Payment Classification payment status indicators in the OPPS unless they meet one of the criteria for packaging, which, with the exception of drug or biological products billed with a Comprehensive Ambulatory Payment Classification (C– APC) service, we do not anticipate that drugs or biological products approved or authorized to treat COVID–19 would meet.[2]

CMS specified that any new COVID–19 treatment that is a drug or biological product, including a blood product, will be paid separately for the remainder of the PHE for COVID–19 when the product is (1) authorized to treat COVID-19 "as indicated in section I. 'Criteria for Issuance of Authorization' of the letter of authorization for the drug or biological product" and (2) when the related EUA authorizes the use of the product in the outpatient setting.[3]

Thus, we urge CMS to ensure that patients have access to CCP in all settings of care authorized by the current EUA by establishing billing codes and reimbursement rates for CCP furnished in outpatient settings, as well as administration codes for the related transfusion services furnished in different outpatient settings. We encourage the reimbursement rate for CCP to be sufficient to cover the substantial costs involved in the collection of CCP and recommend that CMS leverage the uniform payment rate for CCP that was established by BARDA when determining the Medicare payment rate for the product. Similarly, we urge CMS to establish payment rates for the related services that reflect the cost of furnishing transfusion services in various outpatient settings.

If you have any questions or need additional information, please contact Susan N. Leppke (301.547.3962,sleppke@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Liz Marcus (202-303-7980, liz.marcus@redcross.org).

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

cc: Tiffany Swygert, Acting Deputy Director, CMS Technology, Pricing, and Coding Group
Cynthia Hake, Deputy Director, CMS Division of DMEPOS Policy (DDP)
Joshua McFeeters, CMS OPPS Blood and Blood Products

[2] 85 Fed. Reg. 71142, 71159 (Nov. 6, 2020).
[3] *Id.*