



Advancing Transfusion and
Cellular Therapies Worldwide

January 4, 2021

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy (CMS-1736-FC)

Dear Administrator Verma:

AABB appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS) Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems final rule for calendar year 2021. AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. The association is committed to "improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide."

We are concerned that CMS relied on an improper Healthcare Common Procedure Coding System (HCPCS) code to establishment the payment rate for P9099 (Blood component or product not otherwise classified). In the final rule, CMS assigned P9099 a status indicator of "R," and explained that the agency was establishing the payment rate "based on the lowest-paying APC in an APC series for that category of service." Therefore, CMS cross-walked P9099 to P9043, which has a payment rate of \$7.79 per unit. However, AABB does not believe that the agency should use plasma protein fraction (PPF) for rate-setting purposes for P9099 because PPF is distinguishable from separately payable blood components under the OPSS for the following reasons:

- Similar to albumin (P9041), PPF is an injectable biologic with an NDC. NDCs do not apply to blood products.¹ Therefore, PPF should be assigned a status indicator of "K" treated as a drug/biological rather than a blood product under OPSS.
- PPF is "an alternative to albumin for plasma expansion.... Like albumin, it is derived from human plasma and comes as a 5% solution. PPF must contain at least 83% albumin and < 1% can be

¹ Food and Drug Administration, NDC Product File Definitions, available at <https://www.fda.gov/drugs/drug-approvals-and-databases/ndc-product-file-definitions> (last visited 12/18/2020).

gamma globulin.”² Since PPF is used as an alternative to albumin, which is treated as a drug/biological under the OPPS, PPF should also be treated as a drug/biological under this same payment system. It should not be used to establish a payment rate for new blood products.

- Unlike blood components, PPF goes through several processing/sterilization steps. Due to the level of processing, PPF does not carry the same risks of transfusion-transmitted infections or transfusion reactions as blood components. Additionally, unlike blood components, PPF does not improve oxygen carrying capacity and does not enhance coagulation.
- PPF is “... is seldom used because it is associated with more frequent hypotensive and allergic reactions than albumin.”³ Since PPF is rarely used, the reimbursement rate is based on very few claims and should not be used to establish the payment rate for P9099.
- While blood components do not have brand names, PPF is available under different brand names, including Plasma Plex, Plasmanate, Plasmatein, and Protenate.⁴

For these reasons, AABB strongly suggests that CMS crosswalk P9099 to P9070 (Pathogen reduced plasma pool) rather than P9043 for the purposes of assigning a payment rate for P9099. P9099 is intended to “allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA), even though there is no distinct code that describes the service or item.”⁵ While the payment rate assigned to P9070 for 2021 - \$53.10 - remains far too low to cover the costs associated with new blood products, it is a better option than basing the payment rate for P9099 on P9043. We continue to urge CMS to work with manufacturers and the blood community to expeditiously establish new billing codes and provide separate payments for these blood products and services in the hospital outpatient setting.

If you have any questions, please contact Leah Stone at 307-215-6554 or lmstone@aabb.org.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

² Anne M. Winkler MD, Beth H. Shaz MD, Transfusion Medicine and Hemostasis, Chapter 33 – Albumin and Related Products, 2009, <https://www.sciencedirect.com/science/article/pii/B9780123744326000336>.

³ Anne M. Winkler MD, Beth H. Shaz MD, Transfusion Medicine and Hemostasis, Chapter 33 – Albumin and Related Products, 2009, <https://www.sciencedirect.com/science/article/pii/B9780123744326000336>.

⁴ See RxList, Plasma Protein Fraction, *available at*

https://www.rxlist.com/consumer_plasma_protein_fraction/drugs-condition.htm (last visited Dec. 18, 2020).

⁵ Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. September 16, 2020.

Accessed 12/6/2018 at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf> (last visited 12/18/2020)