Advancing Transfusion and Cellular Therapies Worldwide

July 7, 2021

Ms. Irina Akelaitis
Healthcare Common Procedure Coding System (HCPCS) Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C5-09-14
Baltimore, MD 21244-1850

Submitted Electronically via HCPCS_Level_II_Code_Applications@cms.hhs.gov

RE: Healthcare Common Procedure Coding System (HCPCS) Level II Code Public Meeting Comments

Dear Ms. Akelaitis:

AABB appreciates the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) Healthcare Common Procedure Coding System (HCPCS) Level II Code Public Meeting. AABB's comments focus on the following requests: (1) bioMérieux's large-volume delayed sampling (LVDS)-tested leukocyte reduced whole blood-derived platelets (request #21.025) and LVDS-tested leukocyte reduced apheresis platelets (request #21.027); and (2) Cerus' cryoprecipitated fibrinogen complex, pathogen reduced (CFCPR) (request #21.026); and plasma, cryoprecipitate reduced, pathogen reduced, each unit (PCRPR) (request #21.028).

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." AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

I. LVDS-Tested Leukocyte Reduced Whole Blood-Derived Platelets and Apheresis Platelets

We understand CMS's rationale in the preliminary coding recommendation that the LVDS-tested platelets are adequately described by the use of an existing platelet P-code (P9031 for leukocyte reduced whole-blood derived platelets or P9035 for leukocyte-reduced apheresis platelets) plus P9100 (Pathogen test[s] for platelets). Due to this decision, AABB asks that CMS develop updated guidance and educational materials to ensure that providers appropriately bill and code for these products. In addition, AABB has been in communication with bioMérieux and understands that it also plans to request that CMS issue updated billing guidance for P9100.

II. CFCPR and PCRPR

Cryoprecipitated fibrinogen complex, pathogen reduced (CFCPR) and plasma, cryoprecipitate reduced, pathogen reduced (PCRPR) are novel blood products that go through pathogen inactivation

using UVA light and psoralen to reduce the risks of a broad-spectrum of transfusion transmitted infections, including those due to viral, bacterial and parasitic pathogens. In addition, the CFCPR product is unique in that it can be stored up to five days after thawing. We appreciate that the Food and Drug Administration (FDA) awarded "Breakthrough Device" designation for CFCPR, and support CMS' proposed new technology add-on payment for the product that was included in the proposed rule updating the hospital inpatient payment system for FY 2022. AABB believes that CMS' policies should uniformly support patients' access to novel products, and accordingly, requests that CMS reconsider the requests to establish related HCPCS codes.

Conclusion

Thank you for the opportunity to provide comments. If you have any questions or need additional information, please contact Susan N. Leppke at 301.547.3962 or sleppke@aabb.org.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB