



September 5, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

Dear Ms. Brooks-LaSure:

AABB appreciates the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) payment policies under the proposed rule for the physician fee schedule and Medicare Part B payment and coverage policies for calendar year (CY) 2025. AABB's comments focus on the proposals related to CAR-T therapy services and therapeutic apheresis.

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 mission 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. CAR-T Therapy Services (CPT codes 3X018, 3X019, 3X020, and 3X021)

AABB appreciates CMS's recognition of the complexity involved in CAR-T cell therapy by replacing the existing Category III CPT codes (0537T, 0538T, 0539T, 0540T) with new Category I CPT codes (3X018, 3X019, 3X020, 3X021). We agree with CMS's proposal to adopt the Relative Value Scale Update Committee (RUC) recommendations for the work relative value units (RVUs) associated with all four new Category I CPT codes, as well as the practice expense (PE) inputs for CPT code 3X021. Additionally, AABB urges CMS to leverage all available data to ensure that the practice expense costs accurately reflect the resources required for CAR-T therapy. We encourage CMS to continue updating these PE inputs as more data becomes available, ensuring that they remain aligned with the actual costs incurred in delivering these complex and resource-intensive services.

We commend CMS for its comprehensive recognition of the multi-step process inherent in CAR-T cell therapy. This process, as summarized by CMS, includes: (1) lymphocyte harvesting from the patient with cancer; (2) creation of cancer-targeting lymphocytes in vitro using various immune modulators; (3) selection of lymphocytes with reactivity to cancer antigens using enzyme-linked immune-assay; (4) depletion of the patient's remaining lymphocytes using immunosuppressive agents; and (5) transfusion of the cancer-targeting lymphocytes back into the patient with cancer-this transfusion represents one

The Honorable Chiquita Brooks-LaSure

September 5, 2024

Page 2

treatment. Each of these clinical steps is resource intensive, often occurring at different institutions and potentially months apart. The cell collection and processing steps are particularly distinct from the manufacturing of the CAR-T cells and involve significant contributions from both physicians and clinical staff requiring considerable time and resources during each step. Therefore, CMS should finalize its proposal and assign PE inputs for CPT codes 3X018, 3X019, 3X020 based on available data.

II. Therapeutic Apheresis and Photopheresis (CPT codes 36514, 36516, and 36522)

AABB supports CMS's proposal to adopt the RUC-recommended direct PE inputs for CPT codes 36514, 36516, and 36522, which are based on the use of the L056A, RN/oncology nurse clinical labor type. We also encourage CMS to continue reviewing and updating these codes as necessary, especially considering the increasing use of these services within both transfusion medicine and cell and gene therapy.

III. Conclusion

AABB appreciates the opportunity to provide comments on this important proposed rule. Should you have any questions or require additional information, please feel free to contact Susan N. Leppke at 301.547.3962 or sleppke@aabb.org.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB