

September 8, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1832-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program (CMS-1832-P)

Dear Dr. Oz:

The Association for the Advancement of Blood and Biotherapies (AABB) and the American Society for Apheresis (ASFA) appreciate the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) payment policies under the CY 2026 Physician Fee Schedule (PFS). We commend CMS for its continued efforts to reflect evolving clinical practices in transfusion medicine and cellular and gene therapies, and we offer recommendations to ensure patient access, accurate valuation of services, and fair reimbursement for critical, resource-intensive care.

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 advances this mission by developing and delivering standards, accreditation, and educational programs that optimize patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care professionals.

ASFA is an organization of physicians, scientists, and allied health professionals whose mission is to advance apheresis medicine for patients, donors and practitioners through education, evidence-based practice, research and advocacy.

I. Mechanical Separation of Plasma from Blood (CPT code 36514, therapeutic apheresis, plasma pheresis)

Both AABB and ASFA CMS's decision in the CY 2025 Final Rule to adopt the RUC-recommended direct practice expense inputs for CPT 36514 (therapeutic apheresis, plasma pheresis), which utilize the L056A (RN/oncology nurse) clinical labor category, affirming and assuming that the code is appropriately valued. We encourage CMS to continue reviewing and updating these codes as necessary, particularly given the expanding role of therapeutic apheresis in cellular therapies and transfusion medicines.

II. Autologous Cell-based Immunotherapy and Gene Therapy Payment

CMS's proposal to bundle payment for tissue procurement and processing steps (CPT 38225, 38266, 38227) into the payment for the CAR-T product (CPT 38228) reflects the principle that Medicare does not separately reimburse for manufacturing steps considered part of a drug or biological product. However, AABB and ASFA maintain that these steps represent medically significant and distinct clinical services. They require complex decision-making, intensive physician and staff labor, coordination across time and sites, and specialized resources. These services are fundamentally different from manufacturing and therefore warrant separate valuation and reimbursement.

Our prior comments (e.g., CY 2025 PFS and OPFS filings) have emphasized the importance of recognizing and valuing each separate step involved in CAR-T therapy appropriately. As CMS has described, the process 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.

Bundling these services undermines the complexity of care, diminishes physician work valuation, and may discourage providers from engaging in such intensive, life-saving therapies. Furthermore, CMS's proposal to include manufacturer-covered tissue procurement costs in ASP calculations does not address the core issue of undervaluing physician medical decision making and clinical labor in managing critically ill patients in need of these therapies.

Therefore, AABB and ASFA urge CMS to reconsider the bundling policy and reimburse CPT 38225–38227 separately under the PFS, reflecting their true clinical complexity. If bundling remains, we request that CMS provide clear and actionable guidance for reimbursement when the CAR-T product is ultimately not administered (e.g., when a patient cannot proceed after collection). Most importantly, we ask CMS to refrain from extending this bundling policy to other autologous cell-based or gene therapies, as doing so risks broader undervaluation of essential laboratory and physician work across emerging therapeutic modalities.

III. Conclusion

AABB and ASFA appreciate the opportunity to provide comments on this important proposed rule. We look forward to working with CMS to ensure that payment policies reflect the realities of transfusion medicine and cellular therapies, and that patients continue to have access to these life-saving treatments. 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

Peggy Reid, RN, QIA
President
American Society for Apheresis