



September 5, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1809-P  
P.O. Box 8010  
Baltimore, MD 21244-8016

**RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1809-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 hospital outpatient prospective payment system for calendar year (CY) 2025. AABB's comments focus on the proposals related to CAR-T therapy services.

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 Category I CPT Codes (CPT Codes 3X018, 3X019, 3X020 and 3X021)**

AABB notes that the CMS 2025 NPRM Addendum B proposes to delete the existing Category III CPT codes for cell collection (0537T), cell processing (0538T and 0539T), replacing them with the new Category I CPT codes (3X018, 3X019, 3X020) assigned with a status indicator of "B". While we appreciate CMS' recognition of the need for updated coding, AABB requests that CMS assign a status indicator of "S" to these new Category I CPT codes. This would allow for separate payment for these critical clinical services, reflecting the significant resources required for their provision.

We further encourage CMS to assign the most clinically relevant Ambulatory Payment Classifications (APCs) to these codes, leveraging all available data across payment systems to ensure appropriate reimbursement. We commend CMS for acknowledging the necessity of separate payment for these services when provided by clinical staff in physician offices, as outlined in the CY2025 Medicare Physician Fee Schedule proposed rule. It is imperative that this policy is consistent and extends to the hospital outpatient setting, where the same services should similarly receive separate payment under the hospital OPFS.

AABB also applauds CMS for its comprehensive recognition of the multi-step process involved in CAR-T cell therapy. As the agency has summarized, this 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-this transfusion represents one treatment. Each of these clinical steps is resource intensive, often occurring at different institutions and potentially months apart. The cell collection and processing steps, in particular, are distinct from the manufacturing of the CAR-T cell product and should be separately reportable and reimbursable at the time they are performed. For instance, lymphocytes may be harvested at one institution, processed at another, and infused into the patient at a much later date. The associated costs incurred by hospitals for these activities are not captured in the current rate setting or through the payment for the CAR-T product upon administration. Therefore, we urge CMS to treat CAR-T services as distinct clinical services in the hospital outpatient setting and assign appropriate status indicators and APCs to ensure separate reimbursement.

## **II. Exclusion of Cell and Gene Therapies from the C-APC Policy**

AABB strongly supports and urges CMS to finalize the proposal to exclude cell and gene therapies from the comprehensive APC (C-APC) packaging policy for at least one year. As CMS has noted, the administration of these therapies and the therapies themselves are the primary services provided, which do not align with the original intent of packaging under the C-APC policy. Moreover, as more cell and gene therapies transition from pass-through status (indicator "G") to being separately paid under status indicator "K," the packaging of these therapies under status indicator "K" could significantly hinder patient access to these innovative treatments in the hospital outpatient setting. Finalizing the exclusion of all cell and gene therapies with a status indicator "K" from the C-APC policy will be crucial to maintaining patient access to these innovative therapies.

## **III. Conclusion**

AABB appreciates the opportunity to provide comments on this important proposed rule. We believe that the adoption of our recommendations will help ensure appropriate and consistent payment policies that support patient access to vital CAR-T and other cell and gene therapies. 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](mailto:sleppke@aabb.org).

Sincerely,

Debra BenAvram  
Chief Executive Officer  
AABB