



September 11, 2023

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1784-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program; (CMS-1784-P)**

Dear Ms. Brooks-LaSure:

The Association for the Advancement of Blood & Biotherapies, America's Blood Centers and the American Red Cross appreciate the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS) Physician Fee Schedule proposed rule for calendar year 2024. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals. **Our comments focus on potentially misvalued codes: CPT codes 36514 (Therapeutic apheresis; for plasma pheresis), 36516 (Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), and 36522 (Photopheresis, extracorporeal) (hereinafter collectively referenced as "therapeutic apheresis"). We request that CMS (1) establish a new clinical labor code for a therapeutic apheresis nurse with a labor rate reflecting the required skills and experience; and (2) increase the payment rates assigned to these CPT codes to reflect the total cost of the procedures.**

Therapeutic apheresis is a well-established procedure utilized for primary, adjunctive, and supportive treatment for a range of hematological, neurological, renal, and autoimmune disorders. However, the CPT codes for therapeutic apheresis are insufficient to ensure patient access in all care settings where the procedure can be safely performed. Indeed, these challenges of inconsistent and insufficient coverage are present in Medicare as well as various private and governmental insurance options, and often result in patients either forgoing therapeutic apheresis or transferring to a different, and more expensive, care setting to access the procedure.

A medical and nursing team with technical training and experience in apheresis and transfusion medicine is essential to ensure the safety and efficacy of therapeutic apheresis procedures. Therapeutic apheresis is performed in a variety of care settings, including hospitals, clinics, and physicians' offices. In addition, due to the need for specialized and personalized patient experience, variable demand for therapeutic apheresis, and resulting workforce challenges, hospitals and other providers often contract with their existing blood providers to administer therapeutic apheresis via the blood establishment's trained medical and nursing staff and specialized equipment.

Blood establishments often utilize their nursing staff to service multiple hospitals and/or other providers in a region and meet the rigorous scheduling, technical, and compliance demands required by patients who depend on this essential procedure.

Therapeutic apheresis is time-intensive and requires unique and specialized staff involvement compared to traditional medical and nursing models of care. On average, these procedures can require up to four hours of direct patient care, during which time the therapeutic apheresis nurse does not leave the patient's bedside. In addition, the nurse may also need to travel to the care setting, set up the specialized equipment, consult with additional medical and nursing staff, work with the hospital blood bank to acquire blood products as needed, work with the pharmacy for any medication requirements, obtain and consider other medical information such as the patient's blood counts (i.e. electrolytes and coagulation factors), obtain venous access on the patient, run the procedure, manage adverse reactions, document the procedure, and complete and file required paperwork. In total, an entire eight-hour shift of a nurse is often required for a single patient receiving therapeutic apheresis.

On average, specialized apheresis nurses obtain two to six months of additional training prior to overseeing their first therapeutic apheresis due to the complexity of the procedure, the equipment, and the patient's conditions. Required skills outside of general nursing training include an elevated level of competency in performing difficult venipunctures, the ability to perform sterile central line access, cannulate fistulas and grafts, and manage rapid blood product infusion. Specialized apheresis nurses must also have a thorough understanding of specialized apheresis equipment, advanced patient assessment skills, quality management for compliance and more.

Due to the additional training and high demand for specialized nurses, the average hourly wage and annual salaries of these professionals is significantly higher than the labor rate of a general nurse, which is currently used by CMS for therapeutic apheresis. We believe that the establishment of a therapeutic apheresis nurse category with a labor rate reflecting the required skills and experience is an essential step to ensuring appropriate reimbursement for these procedures. In addition to devaluing the labor rate, the total reimbursement for therapeutic apheresis fails to appropriately account for the total cost of these procedures, including blood product costs, additional supplies such as collection kits, additional medical and nursing time, and specialized equipment that requires ongoing maintenance.

Our organizations appreciate the opportunity to provide comments on these misvalued codes and the impacts this valuation has on patient access to care. If you have any questions, please contact Susan Leppke (301-547-3962, [sleppke@aabb.org](mailto:sleppke@aabb.org)), Kate Fry (202-654-2911, [kfry@americasblood.org](mailto:kfry@americasblood.org)), or Julie Manes (202-417-5147, [julie.manes@redcross.org](mailto:julie.manes@redcross.org)).

Sincerely,

Debra BenAvram  
Chief Executive Officer  
AABB

Kate Fry  
Chief Executive Officer  
America's Blood Centers

J. Chris Hrouda  
President, Biomedical Services  
American Red Cross