February 10, 2025

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Finalized CY 2025 Payment Policy for Chimeric Antigen Receptor T-Cell (CAR-T) Therapy

Dear Centers for Medicare and Medicaid Services Representatives:

The College of American Pathologists (CAP) would like to thank the Centers for Medicare and Medicaid Services (CMS) for meeting on February 3, 2025, to discuss our concerns related to the finalized payment policy for Chimeric Antigen Receptor T-Cell (CAR-T) therapy (CPT codes 38225, 38226, 38227, and 38228). The CAP urges the CMS to separately and individually pay for each CPT code through the Medicare Physician Fee Schedule and the Outpatient Prospective Payment System.

While CAR-T services have similarities to the recognized services associated with other gene and cell therapies, they are sufficiently distinct that therapy specific coding is warranted. The CPT Editorial Panel and CMS recognized this distinctiveness and in 2023, the CAP led a multispecialty effort to create and value four new category I CPT codes for CAR-T therapy. Specifically, these codes recognize the harvesting of blood derived T lymphocytes, the preparation and preservation of those collected lymphocytes for transportation to a manufacturing facility, the subsequent receipt and preparation of the modified lymphocytes for infusion into the patient, and finally the administration of the modified lymphocytes to the patient.

Despite this distinct coding, CAR-T services should reasonably be expected to follow similar payment policies used for other gene and cell therapies. The CAP specifically modeled the CAR-T coding after gene therapy with the expectation that it would follow the same payment pathway. Instead, referencing a policy that prevents Medicare from paying separately for each step used to manufacture a drug or biological product, the CMS opted to bundle payment for the harvesting and preparation services (CPT codes 38225, 38226, and 38227) into a drug manufacturing code. **Given the history of recognizing the cell harvesting and administration steps associated with other cell therapies, the CAP disagrees with CMS' decision to identify CAR-T services as part of the manufacturing process and to not pay individually for each service through the Medicare Physician Fee Schedule.**

The CPT codes associated with CAR-T therapy represent separate and distinct processes. Each step is labor intensive and requires the expertise of physicians and professional oversight and monitoring. CAR-T patients are very sick and must be monitored for specific treatment related complications such as, fainting, allergic reaction, seizures, and abnormal heart rate. By not reimbursing for CAR-T services, the CMS is failing to recognize the medical decision making and physician work associated with managing these complex and extremely sick patients. **CPT codes 38225, 38226, 38227, and 38228 represent patient care and management. Providing life-saving emergency care in response to significant treatment related complications should never be considered part of the drug manufacturing process.**

We anticipate additional types of gene and cell therapies that will require cell harvesting and fractionation in the coming years. Therefore, the CAP is asking the CMS to clarify their policy and answer the following questions related to therapies using modified human biologics.

1. Can the CMS provide the specific language of the policy used to bundle the payment of CAR-T services?
2. Can the CMS provide an explanation for why the physician work described by CPT codes 38225, 38226, and 38227 is considered part of the manufacturing process?
3. Does CMS have examples of contracts from CAR-T manufacturers to demonstrate appropriate reimbursement for the physician work performed by outside providers (i.e., not employed by the manufacturer) for the services described by CPT codes 38225, 38226, and 38227?
4. Can CMS provide a rationale for why each manufacturer's product should be paid for through a unique HCPCS Level II code?
5. There are new centers performing their own CAR-T manufacturing. How should these services be reported and reimbursed?
6. Can CMS provide an explanation for the long-standing restriction on stem cell and cell therapy codes. Has this restriction changed over time and is the rationale for that restriction still valid today?
7. By bundling payment, we question where the liability would fall for complications stemming from the cell harvest. Would it fall upon the CAR-T manufacturers as they are responsible for contracting the facility and/or physician?

We encourage the CMS to work with the CAP and other stakeholder experts to reevaluate the CAR-T payment policy and urge the CMS to make appropriate edits to ensure that the physician work associated with CAR-T therapy patient care services is appropriately recognized and compensated. To this end, the CAP also supports the Advisory Panel on Hospital Outpatient Payment recommendations to assign CPT code 38225, 38226, and 38227 a status indicator of S and place 38225 in APC 5242 and 38226 and 38227 in APC 5241.

The CAP is pleased to have had the opportunity to meet and discuss this issue and appreciates your consideration of our comments and questions. We look forward to your responses and hope to continue this conversation. Please direct responses to James Carver at jcarver@cap.org or Todd Klemp at tklemp@cap.org.

Sincerely,

Jan Nowak, MD PhD
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Chair CPT/RUC Subcommittee

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