COLLEGE of AMERICAN PATHOLOGISTS

September 9, 2024

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1809-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1809-P; Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1809-P entitled "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program." As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Our comments in this letter focus on the following subjects included in the proposed rule:

1. New Comprehensive Ambulatory Payment Policy (C-APC) Packaging Structure
2. Ambulatory Payment Classification (APC) Level Changes

1. New Comprehensive Ambulatory Payment Policy (C-APC) Packaging Structure

For CY2025, CMS proposes a policy that would exclude cell and gene therapies from C-APC packaging. We note that on Addendum B, CMS recognizes that cell collection code (0537T) and cell processing codes (0538T and 0539T) which are listed as distinct clinical services. For 2025, these tracking codes will be replaced with CPT codes 3X018-3X020. However, the CMS is proposing a status indicator of B with no payment. If there is no distinct payment, hospitals will face significant operational burden due to CMS' status indicator B assignment, which will result in a rejection of the CPT codes for clinical CAR-T services and will not allow accurate claims processing. These clinical services occur months to weeks in advance of potential CAR-T cell infusion, and are distinct services separate from the manufacturing of the CAR-T cell product and should be allowed to be reported and paid separately at the time they occur. Each service is distinct with their own unique costs, liabilities, and clinical tasks. The work to collect and prepare the cells comes at a cost to the hospital and are not captured in current rate setting or through the payment of the product when CAR-T is administered in the outpatient setting. We urge the CMS to separately assign the following APC's and payment with status indicator S.

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		CAP CY2025 Proposed Rule Recommendation		
HCPCS Code	Short Descriptor	SI	APC	Payment Rate
3X018	Car-t bld-drv t lymphocyt	S	5243	$4,707.85
3X019	Car-t prep t lymphocyt f/trns	S	5241	$431.37
3X020	Car-t receipt&prepj admn	S	5241	$431.37
3X021	Car-t admn autologous	S	5694	$327.68

The CAP convened a CAR-T expert panel of six physicians and multiple CAR-T clinical staff who spent significant amount of time estimating the cost of these services and APC assignments. The CAP and the expert panel believe that the services described and provided by 3X018 are most similar to CPT code 36516 (Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion) and should be assigned to APC 5243. Similarly, we believe that CPT codes 3X019-3X020 align most appropriately with services assigned to APC 5241. CPT code 3X021 has been previously assigned to APC 5694.

The CAP urges the CMS to treat CAR-T services as separate and distinct physician services on the HOPPS. The CMS should do so by assigning payable status indicators and distinct APCs, so that each of the codes have their own separate APC payment. The CAP urges the APC assignments for 3X018-3X020 as shown in the table above.

2. Ambulatory Payment Classification (APC) Level Changes

The CMS is proposing to move surgical pathology tissue exam by pathologist (CPT code 88309) to APC 5673 “Level 3 Pathology” from APC 5674 “Level 4 Pathology”. The CAP disagrees with this proposed change to the APC for CPT code 88309. The CAP believes the data leading to this change in APC level must be flawed. OPPs charge-based cost data were neither designed nor intended to be an accurate estimate of service/procedure level costs at the CPT code level. The hospital charge-based cost data used for OPPS rate-setting allow CMS to estimate costs for purposes of grouping a number of services or procedures (multiple distinct codes) into appropriate clinically and economically homogeneous APCs. These data do not identify actual costs for specific procedures. The costs associated with an 88309 service are much greater than the cost of an APC 5673 “Level 3 Pathology” service, based on physician fee schedule technical component cost differences.

CMS’s proposed change represents a 57 percent decrease in the payment amount and does not align with the much more complex set of resources required to examine these specimens. This service includes complex Level VI surgical pathology evaluation representing the most complex surgical pathology tissue examinations by pathologists requiring arduous specimen preparation. The proposed reassignment creates a resource cost rank order anomaly with other physician services (such as CPT code 88307 APC 5673 “Level 3 Pathology”) and the technical costs will not be fully recovered from each unit of service. We believe the unique complexity of specimens associated with these services warrants a level 4 pathology APC. **The CAP urges the CMS to maintain the assignment of APC 5674 for CPT code 88309.**

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The College of American Pathologists is pleased to have the opportunity to comment on these issues and appreciates your consideration of our comments. Please direct questions Maurine Dennis at mdennis@cap.org, James Carver at jcarver@cap.org or Todd Klemp at tklemp@cap.org.

Attachment

cc: Mitali Dayal
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