ASTCT
American Society for
Transplantation and Cellular Therapy

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-F]

Final Rule Link: https://public-inspection.federalregister.gov/2025-19787.pdf (Published 10/31/25)

Executive Summary of ASTCT asks and CMS Response

1. **Autologous Cell-based Immunotherapy and Gene Therapy Proposals: Average Sales Price, Price Concessions, and Bona Fide Service Fees**

ASTCT asks CMS to refrain from finalizing any proposals associated with ASP calculation in this year's final rule and carefully consider stakeholder feedback before proposing further adjustments in forthcoming policy cycles.

CMS Response: CMS finalized its proposal to continue the existing payment policy for CAR T-cell therapies and to extend it to autologous cell-based immunotherapy and gene therapy; "[u]***nder this policy, the costs of patient-specific cell or tissue procurement and processing remain bundled into the payment for the product."*** (pg.640) CMS responded to a commentor that requested clarification of CMS' interchangeable use of 'cell collection' and 'tissue procurement' in the Proposed Rule by clarifying that "that when the required procurement procedure does not involve apheresis (for example, when starting material is obtained via procedures including, but not limited to, surgical biopsy, tumor harvest, or tumor resection), the term "tissue procurement" remains appropriate in the context of manufacturing autologous cell-based immunotherapy and gene therapy." (pg. 634)

CMS did not finalize its proposal to include the costs of preparation services in the drug's ASP calculation as a price concession; rather CMS clarified that these costs are integral to the manufacturing process and a component of a manufacturer's Cost of Goods Sold (COGs) and can be considered Bona Fide Service Fees (BFSFs) if they pass the four-part test for BFSFs. CMS responded to a commenter's request for clarification on *allogeneic* cell and gene therapy (CMS' proposals were specific to autologous) and CMS stated that the procurement of starting material – "whether patient-derived or donor-derived" – are considered COGs and that if a manufacturer acquires donor cells through a non-purchasing third party (such as a registry), such payments may qualify as BFSFs as well. (pg. 636)

2. **Proposed Efficency Adjustment to Work RVUS**

ASTCT does not support CMS' proposed implementation of an efficiency adjustment for work RVUs of non-time-based services in CY 2026. If CMS does move forward with implementation of an efficiency adjustment, ASTCT recommends that the agency identify specific codes and propose them through rule-making for potential future application. Newly released codes (i.e., those within the last five years, at least) such as CPT code 38228 for CAR-T administration, should be exempted.

CMS Response: Despite broad opposition, CMS finalized the policy to implement a negative 2.5% efficiency adjustment for non-time based codes. In response to comments, the agency revised the policy to exempt additional time-based codes: physical medicine and rehabilitation services, RTM services, and services on the telehealth list. The agency also exempted time-based drug administration codes for CY

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

2026. CMS published a table with the estimated combined impact (including both the efficiency adjustment and the reductions to indirect PE) by specialty. See pages 1738-39 of the file:

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,549	0%	0%	0%	0%
	Non-Facility	$995	0%	6%	0%	6%
	Facility	$555	0%	-11%	0%	-11%

3. Updates to Practice Expense (PE) Methodology – Site of Service Payment Differential

ASTCT recommends that CMS postpone implementing any reduction to the indirect PE RVUs for facility-based physicians. We disagree with CMS' premise that payment for indirect costs for facility-based physicians is being duplicated. The agency should work to collect data, by specialty, that shed better light on the varying levels of indirect practice expense for facility- vs. non-facility-based physicians.

CMS Response: CMS finalized the proposal to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs beginning in CY 2026. CMS will exclude codes with MMM global periods from this adjustment.

(Please refer to the Efficiency Adjustment section for estimated total impact.)

4. G2211 Utilization Assumptions

ASTCT recommends that CMS use available data to ensure that it makes accurate utilization assumptions for CPT code G2211 for CY 2026, and update the budget neutrality adjuster accordingly.

CMS Response: CMS acknowledged that its utilization assumptions for the code were initially too high, but noted it does not make retroactive changes to the budget neutrality adjuster. The agency noted it continues to anticipate that utilization of the code will increase over time and it remains appreciative of feedback on how to encourage its appropriate use.

5. Status Indicator (PC/TC) change for 38228: CAR-T Administration

ASTCT requests that CMS correct the PC/TC indicator of CPT code 38228 from "5" to "0" to appropriately capture the nature of the service being provided and to align it with other similar services (e.g., 38240, 38241, 38242). We request CMS make this change retroactive so that clinicians who received denials during CY 2025 may resubmit claims for payment processing.

CMS Response: CMS agreed with commenters that the assigned PC/TC indicator for the code was "an unintended technical error" and finalized the change from "5" to "0" for CY 2026. (pg. 51) CMS did not indicate that the change was retroactive. Later in the rule, there was an additional discussion of the CAR-T CPT codes where CMS declared additional status indicator changes out of scope for the rule. (pg. 636)

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

6. Proposal to Modify the Medicare Telehealth Services List and Review Process

ASTCT supports CMS' proposals to consolidate the process for adding services to the list of approved Medicare Telehealth Services. ASTCT agrees with CMS' proposal to remove frequency limitations for subsequent visits on a permanent basis. We also agree with CMS' proposal to adopt a definition of direct supervision that allows the supervising physician or qualified health professional to furnish such supervision through real-time audio-visual interactive telecommunications. ASTCT requests that CMS extend the waiver of provider enrollment requirements for CY 2026 and beyond.

CMS Response: There was broad support for CMS's telehealth proposals and the agency finalized several policy changes. These include: streamling the process for adding services to the Medicare Telehealth Services List; permanently removing frequency limitations for subsequent inpatient visits, subsequent nursing facility visits, and critical care consultations; and permanently adopting a definition of direct supervision that allows the physician or supervising practitioner to provide such supervision through real-time audio and visual interactive telecommunications (excluding audio-only). In response to public comments, CMS also finalized allowing teaching physicians to have a virtual presence in all teaching settings.

7. Remote Physiological Monitoring

ASTCT asks that CMS assign OPPS-payable status indicators for RPM codes ("V" for RPM codes focused on intial set-up; "Q1" for subsequent/add-on codes) now so that hospital reporting of these services can be tracked and analyzed for future ratesetting proposals.

CMS Response: CMS did not address this comment as it pertains to OPPS. ASTCT anticipates that CMS may address it in the OPPS final rule.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733