ASTCT Medicare Proposed Rule Comment Summaries

Physician Fee Schedule (PFS) items – comments due 9/12 via
https://www.regulations.gov/docket/CMS-2025-0304

1) **Average Sales Price: Price Concessions and Bona Fide Service Fees**

ASTCT does not support CMS' proposals that 1) preparatory procedures for tissue procurement and/or cell collection be included in the payment of the product itself for autologous cell-based immunotherapy and gene therapies (autoCGTs) and that 2) any payments entities have received for cell collection from manufacturers should be treated as price concessions. ASTCT has repeatedly requested that CMS recognize separate payment for the distinct, provider-furnished clinical services associated with CAR-T therapy, as it does for all other covered clinical services, and maintains that viewpoint after considering this proposal.

CMS' broader proposals to modify ASP calculations are highly technical and beyond the domain of most clinicians but could significantly and negatively impact the payment providers receive when administering lifesaving therapies like autoCGTs. Providers are not typically engaged in the complexities of ASP calculations and have no knowledge of most of the types and scope of arrangements CMS is proposing to define as price concessions. The arrangements between a manufacturer and its distributor(s), data partner(s) and other fee-based contractors are proprietary and outside the sphere of influence for any clinical service provider. Given the personalized nature of autoCGTs, there are very few discounts available to purchasing providers, creating a situation where ASP and acquisition costs have been essentially equal. ***If CMS' proposed price concession assumptions drive the absolute value of ASP+6% (or ASP+3-4%, accounting for sequestration) down significantly, providers will face a net negative impact on acquiring these products for use on Medicare beneficiaries.*** Without a mechanism to understand the net impact to ASP, providers of autoCGTs are left with no choice but to protest the set of proposals in its entirety.

In its proposal to treat payment for tissue procurement and/or cell collection as a price concession, CMS states that these clinical services are "part of the COGS" (Cost of Goods Sold) for these products. This is illogical, as a required manufacturing step cannot also be a discretionary post-production concession to its purchase price. CMS seems to be making multiple unfounded assumptions about cell collection practices, including that most providers are being paid by manufacturers and that the entity collecting cells is the same provider infusing them. CMS has not shared any data as to the volume and/or type of entities that are receiving payment for cell collection services, yet it is proposing to implement an unjustified payment discount across all treating providers.

From an operationalization perspective, finalization of these proposals as written would create an astounding level of provider questions related to compliance, billing, and cost reporting. There is no feasible way to seek and receive guidance on these issues in time for a January 1, 2026 effective date.

Access to autoCGTs for Medicare beneficiaries will decrease dramatically if provider payment is forced below the costs of acquiring these unique therapies, as would be the case with the current proposals. ASTCT understands CMS' focus on drug pricing, but there are other ways to seek partnership with manufacturers and providers beyond implementing negative pressure on ASP methodology. ***ASTCT asks that CMS 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.***

2) Proposed Efficiency 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. We have concerns with CMS' broad assertion that services become more efficient to perform as they become more common. This is not the case for stem cell transplant or cell and gene therapies, for example, due to a continuous influx of new indications and associated new and complex patient populations. ***If CMS does move forward, ASTCT recommends the agency identify specific codes and propose them through rule making for potential future application. CMS should exclude newly released codes (issued within the last five years) such as CPT code 38228, for CAR-T administration, as these codes were surveyed on current clinical practice activities as part of code development and the premise of 'efficiency over time' would not yet be relevant.***

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

ASTCT disagrees with CMS' 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. ASTCT fundamentally disagrees with the basic premise that payment to physicians is being duplicated simply because hospitals receive payment under OPPS or IPPS and/or facility-based physicians receive payment that includes allocation for indirect practice expense. It is not possible for physicians to receive duplicate payment for these costs as hospitals *are prohibited* from reporting physician administrative costs in their cost report per CMS' instructions – therefore, those costs are not reimbursed as part of the OPPS. Additionally, hospital-employed physicians still incur indirect practice expense for things like coding, billing, scheduling, peer-to-peer medical conversations, and prior authorization processes, and these must be recognized and paid by CMS. ***ASTCT recommends that CMS postpone implementing any reduction to the indirect practice expense RVUs for facility-based physicians until a study has been conducted or data collected by specialty that can identify potentially varying levels of indirect practice expense for facility vs. non-facility-based physicians.***

4) **Request for CMS to change Professional Component/Technical Component (PC/TC) indicator of CPT code 38228**

ASTCT disagrees with CMS' assignment of PC/TC indicator of "5" for CPT code 38228 (CAR-T administration), which means that physicians are not paid for this service when providing CAR-T therapy to hospital inpatients (POS = 21) and hospital outpatients (POS = 22). CMS previously allowed the predecessor code (CPT code 0540T) to be paid for in both situations and did not provide a rationale for a change in payment policy when the new code was made effective for CY 2025. ***ASTCT requests that CMS change the PC/TC indicator of CPT code 38228 from "5" to "0" to appropriately capture the nature of the service being provided, align it with other similar services (e.g., 38240, 38241, 38242) and enable physicians providing CAR-T therapy to hospital inpatients and outpatients to receive payment. ASTCT requests CMS make this change retroactive to the beginning of 2025 so that clinicians who were denied payment during CY 2025 may resubmit claims for payment processing.***

Outpatient Prospective Payment System (OPPS) items – Comments due 9/15 via **https://www.regulations.gov/docket/CMS-2025-0306**

1) **Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)**

ASTCT understands and supports CMS' mission to provide care for Medicare beneficiaries in the most cost-efficient way possible. We also appreciate the agency's goals of ensuring Medicare beneficiaries, especially those who are chronically ill and receiving high levels of care, are not subject to needlessly high co-pays. **ASTCT disagrees, however, with CMS' proposal to use its authority to reduce the payment of 61 HCPCS codes assigned to drug administration APCs provided in excepted off-campus PBDs**. Certain locations were grandfathered by Congress, and therefore CMS should not be allowed to change the payment basis from OPPS to the Medicare Physician Fee Schedule (MPFS) equivalent payment rate, as this would effectively reduce the payment hospitals receive for drug administration services to 40% of the OPPS APC rate.

ASTCT also disagrees with CMS' premise that there has been an "unnecessary increase in volume" – meaning, that CMS believes that beneficiaries who can safely receive drug administration in a lower-cost setting are instead receiving services in a higher-paid setting due to payment incentives created by higher OPPS rates. This ignores multiple facts of care provision in the United States – primarily, that hospitals do not scout for patients, rather patients are referred by physicians to hospitals and it is physicians who order the services patients receive at certain locations for based on their care needs. This typically means usually means that hospitals treat patients who are sicker than those seen in physician's offices, *per physician directive*. This is especially true for drug administration services, which can be complex when administered to ill patients with multiple comorbidities and concomitant therapies.

Moreover, for CMS to say that a higher OPPS rate compared to a lower MPFS rate for the same CPT code creates perverse incentives about where patients are treated overlooks the fact that OPPS and MPFS are two different and unique payment systems. The most obvious difference is that CMS develops OPPS rates using the concept of packaging, which MPFS does not. This is a difference that cannot be overlooked as it results in many items and services, including low-cost drugs and biologicals, ancillary

services, lab tests, and minor procedures being packaged into a single payment rate in the hospital while being paid separately in the free-standing physician office.

Additionally, just because the same CPT code appears on claims submitted by different settings does not mean that the services provided are identical. For example, CPT code 96413 indicates that an hour of chemotherapy infusion was provided, but the payment rate for that CPT code under OPPS vs. MPFS conveys something far different, due to the concept of packaging used under OPPS. And while the same OPPS payment is made to both non-excepted and excepted off-campus PBDs for CPT code 96413, CMS cannot assume that the patients being treated are clinically identical or that the intensity of the services provided during the encounter is the same. Just as CMS erroneously compared CPT code 96413 provided in a free-standing physician's office to hospital locations years ago, it is also incorrect to assume that the reduced payment being made to non-excepted off-campus PBDs should automatically be applied to excepted off-campus PBDs and that they will be able to continue to treat complex patients safely and effectively. This is overly simplistic and ASTCT believes CMS must first carefully analyze a range of factors (including patient acuity, complexity, comorbidities, cancer stage, drug regimens, etc.) before making any statements about the similarity of patients in different sites of care. All these factors impact treatment type, cost, and resource intensity far more than any specific CPT® code appearing on a claim.

ASTCT asks that CMS abandon this proposal due to the need for further supporting data and what we believe is a violation of a Congressional directive.

2) **Request for Information (RFI): Expanding the Method to Control for Unnecessary Increases in the Volume of Covered HOPD Services to On-campus Clinic Visits**

ASTCT disagrees with CMS expanding its proposed volume control method to other services – specifically to on-campus clinic visits in the future - because the OPPS and the MPFS are vastly different payment systems. CMS' concept of packaging under OPPS means a wide array of items and services are not paid for separately to hospitals, while they are to free-standing physician offices under MPFS. This means that HCPCS code G0463 is expected to describe a wide array of visits (simple, complex, long, short, etc.) as well as all the items and services that CMS packages into those visits and for which no separate payment is provided. This is in significant contrast to free-standing physician offices that have an assortment of Evaluation and Management (E/M) codes, as well as other visit codes, with corresponding varying payment amounts and no packaging of additional items or services rendered to the patient during the encounter. CMS cannot expect hospitals to be paid a single rate for all types of patient visits and absorb the packaged items and services while facing a proposal to reduce the payment to 40% of the APC rate. This proposal is ill-founded and will exponentially worsen the financial burden hospitals already face when providing comprehensive care to their patients. ***ASTCT urges CMS to forgo further attempts to reduce hospital payments through site neutrality measures.***

3) **Changes to the Inpatient Only (IPO) List**

If CMS finalizes phasing out the Inpatient Only List (IPO) as proposed, ASTCT requests that the agency make explicit that the clinician's judgement is the sole determining factor for whether a patient receives a procedure or service, as an inpatient vs. an outpatient. This is especially crucial for cell and gene therapies (CGTs), given how rapidly treatments are evolving, the type and mix of patients being treated, and the limited number of specialized treatment centers providing these therapies. Additionally, CMS must make it clear to Medicare Advantage Plans that elimination of the list cannot be utilized to aggressively downgrade patients to outpatient or observation status when a clinician has decided that hospital inpatient care is necessary and appropriate. ***ASTCT asks CMS to require MA plans to follow fee-***

for-service coverage and payment standards with respect to clinician orders for inpatient care, and to prohibit site-of-service denials for procedures that are removed from the IPO list.

4) Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

ASTCT does not support CMS' proposed additional changes to Hospital Price Transparency (HPT) requirements for CY 2026, as these will add additional burden to providers and not advance the goal of providing meaningful information so that consumers can plan for the costs associated with their care. Payers are in the best position to provide their members with accurate information about costs and their responsibility, rather than hospitals. ***ASTCT supports price transparency policies that provide patients with clear, accurate information and requests that CMS more closely scrutinize, enforce, and penalize health plans that fail to do their part as required by law.***

5) Proposed Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights Under the Inpatient Prospective Payment System

ASTCT strongly opposes CMS' proposal to introduce a market-based methodology that relies on median Medicare Advantage Organization (MAO) negotiated charges. ASTCT also notes that proposing a methodology for one payment system (IPPS) within the proposed rule of a different payment system (OPPS) does not reflect the intent of the annual rulemaking cycles and will not result in the amount or kind of stakeholder feedback necessary to properly evaluate a proposal.

While ASTCT shares CMS' goal of better reflecting hospital resources for inpatient items and services and appreciate the agency's desire to improve the accuracy of MS-DRG weights, using MAO data as the basis for more accurate payments is misguided. ASTCT is concerned with CMS' characterization and rationale for the current proposal being that the problem is "*highly inflated*" and "*inherently unreasonable*" hospital chargemasters. This assertion ignores decades of Medicare Cost Reporting history, CMS' own guidance in multiple final rules, long-standing guidance from the Provider Reimbursement Manual that allows hospitals to mark-up charges in accordance with their Cost-to-Charge Ratios (CCRs), and also overlooks the reality of IPPS payment formulas – specifically that NTAP and outlier calculations require CMS to estimate cost from provider billed *charges*. The only way for providers to remain compliant with CMS charging requirements while also attempting to ensure that CMS's "calculated cost" adequately represents actual provider cost, is to apply a markup - as CMS itself has described many times is appropriate. In other words, it is CMS's own charging policies that produce the appearance of "highly inflated" charges in hospital chargemasters. If CMS wishes to fundamentally alter hospital charging practices via this proposal, it must first redesign the IPPS payment formulas that rely on CCRs and revise decades of policy. ASTCT has consistently urged CMS through the IPPS rule-making cycle to do exactly that: create a methodology that better accounts for novel therapies and avoids mischaracterizing compliance as abuse.

ASTCT requests that CMS withdraw its market-based weighting methodology and instead 1) evaluate incorporating Medicare Advantage shadow claims into rate-setting and 2) work collaboratively with stakeholders to develop an inpatient payment system that more accurately reflects the resources required to care for Medicare beneficiaries. ASTCT also requests that CMS discuss proposals within the relevant payment system so that affected stakeholders are properly notified and given opportunity for review and comment.

6) Request for APC Reconfiguration and Status Indicator Changes

ASTCT requests that CMS reassign CPT code 38228 from the APC 5694 for Level IV Drug Administration to APC 5242, which is what autologous stem cell administration is assigned to, as this will result in reimbursement that more closely aligns with the resources required to administer CAR-T to hospital outpatients.

ASTCT requests that CMS recognize the importance of digital health technologies and the significant role they play in advancing patient care by recognizing the actual CPT codes released by the AMA for remote patient monitoring (RPM) and changing the status indicator assigned to all RPM codes from "B" to separately payable status indicator "V" or "Q1" depending on the nature of the service.

7) CY 2026 Physician Fee Schedule Proposal Regarding Cell and Gene Therapies

Mirroring out comments to the Physician Fee Schedule Proposed Rule, ASTCT does not support CMS' proposals that 1) preparatory procedures for tissue procurement and/or cell collection be included in the payment of the product itself for autologous cell-based immunotherapy and gene therapies (autoCGTs) and that 2) include any payments providers have received for cell collection from manufacturers as price concessions. These proposals have the potential to drive ASP+6% net payment rates below product acquisition costs for providers, which will decrease access to autoCGTs.

ASTCT asks that CMS 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.

8) Exclusion of Cell and Gene Therapies From the C–APC Policy

In the CY 2025 Final Rule, CMS finalized a policy to not package payment for cell and gene therapies into C–APCs, when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. ASTCT continues to appreciate and support this policy. In this year's PR, CMS stated the following: "For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product specific HCPCS codes, when created, to the C– APC exclusion list."

ASTCT supports this process improvement, as it no longer requires individual stakeholders to advocate for addition to the list when the pass-through status (another C-APC exclusion) time period concludes. Similarly, we ask the CMS provide more information about how stakeholders with HCPCS codes established before this practice should request their code be added to the exclusion list off-cycle from the rulemaking period. As an example, HCPCS code Q2056 for ciltacabtagene autoleucel (a CAR-T therapy) is listed in the July 2025 Addendum B file with a * indicating a change from pass-through status (SI of "G") to a status indicator of "K", which means it no longer would be automatically excluded from the standard C-APC methodology. CMS does not include Q2056 in the proposed exclusions table, but this therapy meets the terms of CGT exclusion per the new policy. ***ASTCT requests that Q2056 be added to the exclusions table and that CMS share a preferred process for existing codes to request exclusion off-cycle from the rulemaking process as those codes lose pass-through status.***