ASTCT
American Society for
Transplantation and Cellular Therapy

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

September 12, 2025

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: 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-P]

Dear Administrator Oz:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comment letter regarding the CY 2026 MPFS Proposed Rule.

ASTCT is a professional membership association of more than 3,900 physicians, scientists, and other health care professionals promoting hematopoietic stem cell transplantation (SCT) and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration approvals for chimeric antigen receptor T-cell therapy and SCT gene therapies for genetic immune system and blood disorders. For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases.

ASTCT would welcome the opportunity to meet with CMS and discuss ways to improve payment for CAR-T, SCT, and other cell and gene therapies.

If CMS has any questions regarding these comments, please contact Molly Ford, ASTCT's Director of Government and Payer Relations, at mford@astct.org.

David Porter, MD
President, ASTCT
2025-2026

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Executive Summary

ASTCT appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the FY 2026 Medicare Physician Fee Schedule (MPFS) Proposed Rule (PR). The following is a summary of our requests from this letter.

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

ASTCT does not support CMS' proposals to include cell collection costs in a product's payment or to treat fees associated with cell collection as price concessions.

Providers are not typically engaged in the complexities of ASP calculations and have no knowledge 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. Additionally, 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% down significantly (ot ASP+4%, accounting for sequestration), 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 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 does not make sense, as a required manufacturing step cannot also be a discretionary post-production concession to its purchase price. ASTCT suspects that CMS is assuming that manufacturers are paying providers for cell collection and that, therefore, an equivalent amount should be reduced from the ASP-based payment to the provider administering the autoCGT. ASTCT counters that CMS is making multiple assumptions about cell collection practices, including that most providers are being paid by manufacturers at all and that the entity collecting cells is the same as the provider infusing them.

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 likely 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 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.

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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.

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.

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.

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.

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.

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.

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

CMS should pay providers separately for cell collection

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. We maintain this viewpoint after considering this proposal. For an individual beneficiary with blood cancer, a physician evaluates multiple treatment options and determines that provision of CAR-T will be the most efficacious for that individual. In such a situation, collecting a beneficiary's stem cells requires a series of complex and personalized clinical decision-making; the engagement of experienced staff working in specialized clinical settings; and the use of highly technical equipment. This process is significantly different from typical pharmaceutical manufacturing based on plant- or chemically-derived base materials. These distinct clinical services are ordered by treating specialists and furnished by hospitals. *Manufacturers have no purview on these services and the hospitals are fully responsible for the individualized clinical care of the beneficiary*.

ASTCT does not support CMS' proposal that 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).

COGS cannot also be price concessions

CMS states that these clinical services are *"part of the COGS"* (Cost of Goods Sold) for these products, which is in direct opposition to its proposal that payment for these services should be treated as a price concession.

The OIG report cites Section 1847A(c) of the Social Security Act in defining price concessions as "volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks and rebates other than those obtained through the Medicaid Drug Rebate Program." The examples listed are truly price concession – i.e., *concessions or discounts to the purchase price of a drug by a customer*. These discounts are fundamentally different than the processes and costs (the COGS) that go into the actual production of a drug or biologic.

CMS' focus on allogeneic products makes this even more clear, stating: "*In addition, if certain therapies could be scaled in a way that they could be allogenic in nature, we see that the tissue procurement step would even more clearly be considered a manufacturing step. (90 FR 32547)".* CMS is correct that allogeneic therapies would not be possible without the acquisition of cells, either in a one-to-many (off-the-shelf or "universal") or a one-to-one relationship. The cells would be from a donor; therefore, those costs would clearly be up to the manufacturer to bear as part of the manufacturing process, leaving no justification for treating those costs as a price concession.

Given CMS' stated view of cell collection as part of COGS for autoCGTs, CMS should regard these services as a bona fide service fee, not a price concession; in CMS' own words, they are, instead, a ***"pivotal part of the manufacturing process"*** and should be treated as such.

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ASTCT suspects that CMS' proposal to treat cell collection as a price concession partially stems from a belief that providers are being paid at two time points: first by manufacturers for cell collection, and later by CMS for the product administration. CMS' proposal implies that payment the infusing provider receives should be reduced by the amount they received as compensation for cell collection by manufacturers at an earlier time point. Working from this premise, ASTCT notes that CMS is making multiple assumptions about cell collection practices that ASTCT does not believe to be substantiated, including that most providers are paid by manufacturers currently (or will be in the future) and that the entity collecting cells is the same as the provider infusing them. Hospital capacity for apheresis is a concern and alternative models are being considered. If a manufacturer chooses or needs to contract with a third-party entity that has apheresis capabilities, then the infusing provider is not receiving any payment for those services and continues to pay full cost for acquisition of the product. 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 based on this premise.

ASTCT does not support CMS' proposal that any payments entities have received for cell collection from manufacturers should be treated as price concessions.

CMS' proposal will cause significant operational challenges and questions

If CMS finalizes these policies, providers may view them as a mandate to seek reimbursement from manufacturers. But, there are multiple complications would result from a patient's hospital being, essentially, "under arrangement" to a manufacturer for a portion of the patient's care. Our members have accordingly raised a number of operational questions related to CMS' proposals.

Hospital concerns are particularly acute for centers that perform the initial cell collection and also infuse a product at a later point – these patients are being treated for their cancer and will likely receive active treatment for their condition on the same date of service as their collection. Per CMS' 2008 Final Rule, *"[i]t is extremely important that hospitals report all HCPCS codes consistent with their descriptors, CPT and/or CMS instructions and correct coding principles, as well as all charges for services they furnish, whether payment for the services is made separately or packaged." (72 FR 66634)* Hospitals seeking to comply with this requirement would need a mechanism by which they could still bill all services provided to a patient and indicate which specific services should be considered non-payable by CMS.

If it finalizes the proposal, CMS will need to issue guidance as to what specific codes or services are included in its scope, release new modifiers or data elements so providers can still report all services provided to patients, and modify cost-report instructions to account for potential changes to how cell collection, lab processing and product costs flow into the overall hospital cost-to-charge ratio calculations.

ASTCT asks that CMS consider alternative options for autologous cell and gene therapies

CMS has made clear that drug pricing is a priority of the administration. ASTCT supports this premise, as our member clinicians are highly aware of the financial devastation that a diagnosis of cancer or other

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severe illness has on Medicare beneficiaries. ASTCT also acknowledges that the therapies used by our membership are many of the most expensive products approved for use by the U.S. Food and Drug Administration (FDA). However, CMS has multiple ways to support beneficiaries in accessing cutting edge therapies that do not involve a financial loss to the providers that are interested in administering them. These include expansion of its highly successful CMMI Cell and Gene Therapy Access Model to include Medicare beneficiaries and additional therapies, and/or partnering with expert cell and gene therapy programs to reimburse for in-house manufacture of certain cell and gene therapies.

The ASTCT remains ready and willing to meet with CMS for additional discussion of alternatives.

Providers need more time to evaluate and consider CMS' proposals

In this year's rule, CMS proposes multiple modifications to the ASP calculation – all of which will impact ASP-based payment. Yet, the agency has not given stakeholders sufficient time to decipher and comment on highly technical calculations, many of which are far beyond their usual areas of expertise.

ASP calculations and reporting are primarily understood by a limited number of experts within CMS or at drug manufacturing organizations and are very rarely discussed in the MPFS PR. The changes that CMS is now proposing will directly and substantially impact provider payment almost immediately (January 2026), with little time for non-expert stakeholders, such as ASTCT physicians, to understand and respond to the proposals. There is even less time for CMS to analyze and thoughtfully incorporate stakeholder comments into the final rule.

CMS' proposals 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 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. 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.

If CMS' proposed price concession assumptions drive the absolute value of ASP+6% down (or ASP+4%, accounting for sequestration), providers will face a net negative impact on acquiring these products for use with Medicare beneficiaries. 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. Finalizing the proposal as written creates a significant risk of decreasing Medicare beneficiary access to autoCGTs.

ASTCT's requests that CMS delay implementation of any ASP proposals and, instead, allow another rule-making policy cycle in which to consider stakeholder feedback.

Proposed Efficency Adjustment to Work RVUS

CMS is proposing a negative two and a half percent (2.5%) adjustment to more than 7,000 non-time-based codes starting in 2026 and is also proposing that this efficiency adjustment be applied every three

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years. CMS is proposing to apply the efficiency adjustment to the work relative value units (RVUs), as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services. CMS stated in the proposed rule that the agency believes that non-time-based procedures become more efficient as they become more common, professionals gain more experience, technology is improved, and other operational improvements are implemented. CMS also stated that there is typically a two-to-three year time lag between when survey data were collected and when CMS uses the data in rate-setting. CMS is proposing a five-year look-back period for the initial application of the efficiency adjustment, thus the 2.5% figure was derived by tallying the last five years' private, non-farm, productivity adjustments in the Medicare Economic Index (MEI).

ASTCT does not support CMS' proposed implementation of an efficiency adjustment for work RVUs of non-time based services in CY 2026.

ASTCT has concerns with CMS' broad assertion that all services become more efficient to perform as they become more common. While this may be true for some services, painting all physician non-time based services with a broad brush fails to take into account the increasing complexity of medicine as well as the development of novel therapies. Ensuring that Medicare beneficiaries have access to the most current treatments depends in large part on proper evaluation of the cost of these services and the work that physicians do to provide them.

Cell and gene therapies are a prime example of services that can become increasingly complex as they become more common. While ASTCT's clinicians have been providing these since 2017, the class is still evolving. CMS cannot assume an experiential efficiency simply because clinicians have treated more patients. In fact, ASTCT clinicians reported that the more patients they see in the stem cell transplant and cell and gene space, the more diverse and complex these patients are. Treating cancer patients and others who might be candidates for cell and gene therapies is truly new; clinicians are still learning about the cell and gene therapies and how to treat these diseases.

Even if CMS' assertion that services become more efficient with frequency were true, a uniform -2.5% reduction in the work RVUs is not appropriate. Any change to the RVUs should, instead, be based on a more detailed review of the resources involved in rendering services at the CPT code level. As CMS notes in the discussion, codes that were flagged for re-revew are only recommended for a decrease in RVUs by the Resource Utilization Committee (RUC) less than 40% time. This outcome indicates that resource use and effort are largely consistent across time. Additionally, repeating these cuts every three years in perpetuity will quickly result in values that are non-sustainable and, over time, will eventually reach zero. **ASTCT strongly urges CMS not to finalize this proposal. However, 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 (those within the last five years, at least) such as CPT code 38228 for CAR-T administration, should be exempted.**

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

For 2026, CMS proposes a significant change to the practice expense methodology. The proposal would reduce the work RVU input (a key input for the indirect component of the facility PE RVU formula) to 50

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percent of the amount used for non-facility PE RVU computation. This is a substantial change, as the work RVU in the PE formula serves as a proxy for how much time indirect resources use when providing a service.

ASTCT does not support CMS' proposal given we fundamentally disagree with CMS' premise that payment for indirect costs for facility-based physicians is being duplicated.

We appreciate and support CMS' mission to ensure that Medicare dollars are being spent appropriately. However, we disagree with CMS' basic premise that payment for indirect costs for facility-based physicians is being duplicated. Physicians who provide services in a facility-setting incur indirect practice expenses. This is true regardless of whether they are employed by the facility or are private practice physicians with privileges at a facility. Further, CMS's own guidance to hospitals (detailed in Part 1 of the Provider Reimbursement Manual) makes clear that physician administrative costs are *excluded* from what hospitals can report as allowable hospital costs in the cost report.

Section 2110.4 of the cost resport instructions preclude hospitals from including professional billing costs as allowable costs. Professional billing costs necessarily include coding, medical records, scheduling, billing, peer-to-peer medical conversations, and prior authorization requirements, among others. They can *only* be recouped through MPFS due to the aforementioned prohibiltion on hospitals claiming these costs. For CPT codes that are primarily performed in facilities, the PE RVUs should already reflect the necessary indirect costs based on CMS' current allocation methodology, and should not be reduced. We appreciate that CMS has requested input on whether its proposal is appropriate, but CMS' request also bolsters our concern that it is inappropriate to propose a reduction without better understanding the data.

ASTCT recommends that CMS postpone implementing any reduction to the indirect PE RVUs for facility-based physicians. In the meantime, 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.

G2211 Utilization Assumptions

In 2024, CMS implemented a new add-on code G2211: *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.*

Medicare claims data analysis indicates that the utilization of this code was greatly overestimated at the time of implementation. This overestimation dramatically impacted the Medicare conversion factor via a budget neutrality adjustment and, thus, negatively impacted physician paymemt. This overestimation is still impacting the MPFS today.

Beginning with this rulemaking cycle, CMS has access to actual utilization data for this code from 2024. The data show that the initial utilization of this code was greatly overestimated. CMS should ensure utilization assumptions for CY 2026 are adjusted for this initial overestimation. Accurate utilization

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assumptions for G2211 are especially important given the agency's proposal to expand the use of this code to home and resident E/M visits.

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

Status Indicator PC/TC change for 38228: CAR-T Administration

CPT Code 38228: Status Indicator Update

In May 2023, the CPT Editorial Panel approved the addition of four new codes to report CAR-T services, which replaced existing Category III codes. A new subsection in the CPT book with guidelines was also released. The various codes describe steps of a complex process that involves physicians either performing or supervising the service.

ASTCT is specifically concerned about CMS' treatment in the MPFS of CPT code 38228 - *Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*. Patients and healthcare providers invest significant time, spanning weeks or even months, in preparation for the administration of this product, which is patient-specific. CAR-T administration encapsulates the stressors inherent in treating patients in an advanced state of illness, for whom CAR-T therapy represents a personalized and often last-chance intervention.

The RUC forwarded recommendations for CMS' consideration for CY 2025 when the codes were finalized and CMS shared these in the CY 2025 OPPS Proposed Rule. CMS indicated active pricing for code 38228 (administration of autologous CAR-T) by assigning a work RVU of 3.00 and RUC direct practice expense inputs. ASTCT was pleased to see this, as it reflected expectations based on the multi-society work effort in securing these codes through the CPT and RUC processes. Moreover, it aligned with the separate payment policy for the predecessor Category III CPT code 0540T irrespective of whether CAR-T was administered in a facility or non-facility setting and signaled separate payment would continue for the new Category I CPT code.

In reviewing the files released with CY 2026 MPFS final rule, ASTCT noticed that CMS assigned a PC/TC indicator in the MPFS RVU file of "5" ("incident to") to CPT code 38228. We belive this is an error as CPT code 38228 should not be categorized as an "incident to" service. The predecessor code was not designated as an "incident to" service and CMS had assigned a PC/TC indicator of "9," which appropriately allowed facility-based physicians to be paid under carrier pricing.

The AMA/CPT subsection guidelines for CPT code 38228 also make clear that this is a physician service. The guidelines state, *"The procedure to administer CAR-T cells includes physician or other qualified health care professional monitoring of multiple physiologic parameters, verification of cell processing, evaluation of the patient during, as well as immediately before and after the administration of the CAR-T cells, direct supervision of clinical staff, and management of any adverse events during the administration..."*

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When CPT code 38228 is billed by the facility-based physician on a 1500 professional claim with a facility POS (21 or 22), it signifies that the physician (or other qualified non-physician practitioner) personally supervised the initiation of the product infusion; was present for the first 15 to 30 minutes of the service; and remained immediately available to manage toxicities and complications that may occur during the infusion. The physician evaluates the patient at the end of the infusion and documents all of the activities in the patient's medical record.

ASTCT has concerns about CMS' PC/TC indicator assignment of "5" to CPT code 38228 for two reasons. First, CMS did not discuss this intended change in the CY 2025 MPFS proposed rule, otherwise we and other stakeholder groups would have submitted detailed comments at that time.

Second, clinicians have contacted ASTCT and shared they have received denials from their MACs for billing CPT code 38228 on their 1500 professional claims with a hospital POS (21 or 22) given the PC/TC indicator assignment of "5" signifies non-payment in the facility setting. As the majority of CAR-T is still provided to hospital inpatients and outpatients (rather than in the office setting), and the predecessor Category III CPT code 0540T resulted in separate payment through carrier pricing for facility-based physicians, we believe CMS inadvertently assigned the wrong PC/TC indicator to CPT code 38228.

During the process of petitioning for this CPT code alongside other stakeholders, 38228 was positioned as similar to CPT codes 38240-38243 (stem cell transplant codes), as these codes also signify physician involvement in the delivery of the service. To that end, the best analog code for the PC/TC indicator for CPT code 38228 is CPT code 38241, for an autoSCT, that has a PC/TC indicator of "0." This identifies codes that describe physician services where the PC/TC concept does not apply since professional services cannot be split into professional and technical components, which is true for stem cell transplant services as well as CAR-T administration.

Therefore, 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). This will enable physicians providing CAR-T therapy to hospital inpatients (POS = 21) and hospital outpatients (POS = 22) to receive payment.

Additionally, given that CMS has allowed payment for the predecessor code in the past, ASTCT requests CMS make this change retroactive so that clinicians that received denials during CY 2025 may resubmit claims for payment processing.

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. We agree that the most applicable and important criterion is whether a service can be furnished using interactive, two-way audio-visual technology.

ASTCT also agrees with CMS' proposal to remove frequency limitations for subsequent visits on a permanent basis and 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.

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ASTCT requests that CMS extend the waiver of provider enrollment requirements for CY 2026 and beyond. The waiver permits practitioners to bill from their currently enrolled location when providing telehealth visits from their homes, rather than enrolling their home address in order to bill for the service.

Allowing the waiver to expire at the end of 2025 would create a significant amount of additional and unnecessary administrative burden for providers and accordingly reduce beneficiaries' access to telehealth. In addition to privacy concerns, the home address requirement will create cross-MAC complexity when provider home addresses are in a different region from their place of employment.

Remote Physiological Monitoring

ASTCT appreciates that CMS's proposals support the AMA's expansion of CPT codes for Remote Patient Monitoring (RPM) services. As our members continue to expand the use of remote monitoring to support care for their patients after stem cell transplant or cell therapy treatments, it is critical that these services be recognized by CMS. To better serve their patients, our members are setting up post-treatment RPM protocols that include the use of 24/7 tracking of vital signs through biometric sensors[1] and assessing neurocognitive function through electronic surveys and tests.[2]

The current status indicator of "B" assigned to these codes will will undermine CMS' interest in collecting more data on the usage of these codes.

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.

ASTCT appreciates CMS' review of our comments and would be pleased to engage on any technical questions the agency may have.

[1] Moore SL, Peterson GJ, Montoya SR, et al., "Using technology for patient-centered care at home after CAR T-cell therapy or stem cell transplant: a prospective feasibility study," *Front Immunol*. 2025 Jun 18;16:1403249. doi: 10.3389/fimmu.2025.1403249. PMID: 40607376; PMCID: PMC12213405.
[2] Wilemon T, "VICC launches new telehealth program for CAR-T patients," *VUMC News*, February 28, 2019. Online: https://news.vumc.org/2019/02/28/vicc-launches-new-telehealth-program-for-car-t-patients/

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