ASTCT
American Society for
Transplantation and Cellular Therapy

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

September 2, 2024

Submitted electronically at www.regulations.gov

Re: 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; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the Calendar Year (CY) 2025 Outpatient Prospective Payment System (OPPS) Proposed Rule.

ASTCT is a professional membership association of more than 3,900 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. The clinical teams in our society continue to develop and implement clinical care standards which advance the science of cellular and stem-cell based gene therapies.

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 members are involved in the infusion of chimeric antigen receptor t-cell (CAR-T) therapies and other cell therapies to treat blood cancers and for solid tumors, due to the specialized expertise required to safely administer these products in the clinical setting. Additionally, ASTCT members are at the forefront using genetically edited hematopoietic stem cells for the treatment of genetic blood disorders, including beta thalassemia and sickle cell disease, along with immune deficiency and metabolic disorders.

The advent of novel cellular immunotherapies and gene therapies have highlighted challenges within the Medicare coverage, coding, and payment systems. ASTCT remains concerned about the potential barriers to care these challenges may cause. We are committed to working with

CMS to find solutions that ensure patient access to these therapies without creating financial harm to the clinicians who provide them.

To that end, ASTCT wishes to comment on several aspects of the CY 2025 OPPS proposed rule. As explained further in our letter, ASTCT requests that CMS:

- Move forward with its proposal to exclude cell and gene therapy products with status indicator "K" from C-APCs in CY 2025 and beyond;
- Finalize the proposed status indicator "S" for new CPT code 3X021; and
- Change its proposed status indicator for new CPT codes 3X018, 3X019 and 3X020 from "B" to "S".

ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions that CMS may have. Please contact Alycia Maloney, ASTCT's Director of Government Relations, at amaloney@astct.org for any follow-up issues.

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President, ASTCT

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I. Proposal to exclude cell and gene therapies from C-APCs for CY 2025

ASTCT appreciates and agrees with CMS' proposal to exclude the cell and gene therapies included in Table 1 from packaging into Comprehensive APC (C-APCs) in CY 2025 and encourages CMS to finalize this change permanently despite the agency having proposed it for only one year. We also appreciated hearing CMS' description during the August 26th HOP Panel that the packaging of cell and gene therapies into C-APCs is an unintended consequence, which is why the agency has made this proposal for CY 2025. ASTCT agrees with CMS' commentary in the proposed rule that these are independent therapies that are the foci of the treatment encounter and cannot be described as simply "promoting beneficial outcomes" or "prevent possible complications" of another procedure, as discussed on p. 59202 of the Federal Register. The exclusion of these therapies from being packaged as part of C-APC logic will allow

providers to make the best possible treatment decisions for their patients without facing unintended negative financial consequences when a product's pass-through status expires, and the therapy subsequently becomes packaged into a C-APC instead of being paid under the Average Sales Price (ASP) + 6% methodology required by statute.

Inclusion of other drugs, therapies or classes of products

In response to CMS' solicitation for information on adding other cell and gene therapies to Table 1 as well as other therapies or classes of products that should be excluded from C-APCs, ASTCT continues to feel strongly that all status indicator "K" drugs should be excluded from C-APC packaging on a permanent basis. In 2023, the Hospital Outpatient Panel (HOP) agreed with ASTCT's presentation on the exclusion of all SI "K" drugs and issued the following:

> *Recommendation 8*: *The Panel recommends that CMS no longer package drugs with an SI of K into any comprehensive APC; instead, CMS should continue to provide separate payment for all drugs and biologicals above the drug packaging threshold.*[1]

During the CY 2025 HOP Meeting, the Panel again voted in favor of ASTCT's recommendation that all status indicator "K" drugs should be excluded from C-APC packaging. We appreciated the Panel's reaffirmation of support and urge CMS to adopt the Panel's recommendation.

While we recognize the concept of packaging under OPPS, we do not believe it is appropriate for CMS to package any/all drugs simply because they have a status indicator of "K" vs. "G" and happen to be reported on the same claim as a service that has been designated a C-APC candidate (status indicator "J1" and "J2"). We note that products that have been assigned a SI of "G" via the transitional passthrough new technology application process are inherently being recognized as innovative treatments; they do not lose those clinical characteristics when they shift from "G" to "K" and should accordingly retain separate payment status. They do not meet the definitions of integral, ancillary, supportive, dependent, or adjunctive and are priced above the drug packaging threshold; therefore, a permanent exclusion from C-APCs is appropriate and results in payment consistent with the statute at ASP + 6%.

An analysis of CY 2022 claim data showed that the proportion of status indicator "K" drug charges relative to all other charges appearing on C-APCs claims was less than 2.5% across all C-APCs. This confirms two things; first, the nature of CMS' C-APCs, which are primarily surgical and device-intensive in nature, do not inherently involve the provision of SI "K" drugs and second, when they do it is so infrequent that it reflects an anomaly and perhaps even miscoding; thus, a permanent exception is reasonable and should be straightforward to implement. Moreover, given what the data shows, it seems unnecessarily procedural and burdensome to create and maintain an ongoing list of specific drugs that different stakeholders may analyze and petition CMS to exclude based on various rationale, when the simplest policy

[1] https://www.cms.gov/regulations-and-guidance/guidance/faca/apc-panel-archives/1094413198/august-22-2022-hop-panel-meeting-materials-recommendations-and-rebroadcast

for all would be to remove them entirely. We note that CMS will need to monitor all status indicator "G" drugs changing to status indicator "K" on a quarterly basis and determine whether they are cell and gene therapies, whereas this work would not be necessary if status indicator "K" drugs were excluded from packaging altogether. Therefore, we urge CMS to finalize what it has proposed for CY 2025 which is to exclude the cell and gene therapies in Table 1 from packaging into any C-APC, and we urge CMS to think more broadly and implement a broader packaging change for C-APCs, such that no status indicator "K" drugs are packaging into any C-APC.

Time period for implementation

In response to CMS' solicitation for feedback on the timeframe for exclusion, ASTCT requests that CMS implement this policy on a permanent basis for the reasons described above knowing that it can revisit the policy in the future, if necessary.

Potential future C-APC or packaged payment policy for CAR-T

The ASTCT feels strongly that the future creation of a C-APC or some other packaged payment policy for CAR-T (and other cellular and/or gene therapies) would be highly problematic for several clinical and operational reasons. The clinical processes associated with CAR-T are spread out over weeks to months (clinical evaluation, cell collection, receipt of product from the manufacturer, and lymphodepletion of the patient), and are driven by an individual patient's health status in conjunction with product manufacturing capabilities and timelines. A treating physician may need to stop and start aspects of the CAR-T treatment process multiple times at various junctures based on the individual patient's disease status. For example, physicians may need to order additional therapies be administered to patients to temporarily decrease disease burden while a CAR-T product is being manufactured – i.e. use of a 'bridging' therapy or regimen – and to have these therapies, along with other clinical services, inappropriately swept into a C-APC where a single payment is typically made, would be highly problematic. If CMS attempts to implement some type of "episode C-APC" for CAR-T administration, it will result in unfair and woefully inadequate payment to the providers authorized to furnish these types of therapies to hospital outpatients.

Additionally, the use of a C-APC increases the risk that beneficiaries will be adversely financially impacted when receiving CAR-T therapy. As the provision of CAR-T has increased in the years since the initial approvals, the distinct clinical services prior to CAR-T administration are increasingly being provided by different entities that may bill CMS independently for the services (i.e., the entity that collects cells may be a different entity than the hospital or independent physician practice that administers the CAR-T product). When the hospital arranges for an outside entity to perform the services for its registered inpatients or outpatients on hospital premises, we understand that CMS' "under arrangement" rules (42 CFR § 411.15) require hospitals to ensure their arrangements discharge the liability of the beneficiary or any other person to pay for the service. ASTCT is aware that these requirements associated with "under arrangement" services do not apply when the other entity is a separate provider in their

own right and performs the services in their own clinical space. However, by continuing to neither acknowledge the potential variation in arrangements and treatment patterns nor pay separately for the services, CMS will inadvertently create much confusion regarding what entity is responsible for billing and which entity is eligible to receive payment given one hospital or entity furnishes the cell collection and outbound lab processing while another receives the CAR-T product, furnishes dose preparation services, and administers the product.

Given the number of services that could be provided to a patient over time, and by multiple entities, coming up with a single "episodic" C-APC payment that attempts to encompass all aspects of the care process even on average, seems unnecessarily complex and will almost certainly result in placing undue administrative, operational, and financial burden on hospitals, which ASTCT cannot support. Furthermore, the claims data is likely to be fraught with errors given the unprecedented nature of such a C-APC. One example of this is that if CMS were to create an episodic C-APC that were to include HCPCS codes that CMS notes are associated with CAR-T therapy (0537T-0540T; soon to be 3X018-3X020), a hospital attempting to bill for the services rendered would find itself having to depart from how it typically submits claims.

Most outpatient hospital services are billed on a single claim—that is, on a per-day basis—except for certain therapy services that are required to be billed on a monthly claim. The only existing correlation/equivalent would be "repetitive services", as described in 100-04, Chapter 1, Section 50.2.2, which are required to be filed on a monthly or conclusion of treatment cadence. CAR-T services do not meet this requirement or fit the mold of a repetitive services and certainly would not be predictable and simple claims. In fact, in 2005, CMS removed chemotherapy and radiation therapy from its monthly repetitive services billing policy in recognition of the fact that these claims, should be submitted to CMS as they occur, by date of service, which enables easier and faster claims processing, and also enables hospitals to be paid in a timely and appropriate fashion. To deviate from this by moving towards some form of episodic claims preparation or reprocessing of claims etc. to support C-APC payment, where it is not appropriate, again seems unnecessarily complex and burdensome and not something that we see the agency in need of creating for the small volume of cell and gene therapies being provided to hospital outpatients.

Existing C-APCs do not require unique or complex billing requirements. In fact, current C-APCs package payment for services furnished during a single encounter, which typically is one calendar date-of-service. Since the inception of OPPS, CMS has not redefined a single encounter as a multiple-encounter episode to be billed on a single claim where an episode crosses multiple dates of service over multiple months. It would be extremely burdensome for providers to identify, hold, and finally aggregate "all related services" on a single claim as charges would need to be held for weeks or months, which would be a radical departure from current institutional claims billing rules and existing C-APCs. CMS already requires unusual and complex billing for CAR-T clinical services in the outpatient setting[2]; to further extend that places a unique burden on providers that offer this service compared to other drugs and treatments. Our related recommendation to assign SI "S" to CPT codes 3X018, 3X019, and

[2] CMS MLN Matters SE19009, released March 17, 2022.

3X020 would enable CMS to eliminate the complex billing requirements while paying providers for the clinical services they provide (as described in the following section) and would come as a welcome relief to the existing confusion and burden providers experience today. We also note that there would be significant rate-setting adjustments such an episodic C-APC would entail that would be unnecessarily complex and burdensome on CMS to ensure even a modicum of reasonable payment.

Finally, in other sections of the Proposed Rule, CMS discusses two situations in which prior packaging decisions have had detrimental impacts to access and where CMS is proposing or implementing to modify prior policy –diagnostic radiopharmaceuticals and non-opioid pain management. We believe if CMS proceeds with creating a C-APC for cell and/or gene therapies, it will find itself in a similar situation necessitating more unpackaging decisions.

As part of its proposal to 'unpackage' diagnostic radiopharmaceuticals, CMS states the following:

> *As we have reiterated over the years, we believe packaging policies are inherent principles of the OPPS and are essential to a prospective payment system.* ***At the same time, we have explained that we are committed to ensuring beneficiary access to diagnostic radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries.***
>
> *…* ***In situations where a hospital may have to pay significantly more to purchase a diagnostic radiopharmaceutical than Medicare pays, a hospital may decide not to provide that specific diagnostic radiopharmaceutical imaging agent to Medicare beneficiaries.*** *This could potentially deny access to diagnostic tools for which there is no clinical alternative.* ***To ensure Medicare payment policy is not providing a financial disincentive to using high cost, low utilization diagnostic radiopharmaceuticals, especially when those agents may be the most clinically appropriate, and to ensure appropriate beneficiary access, we believe a subset of diagnostic radiopharmaceuticals with higher per day costs should be paid separately and not packaged into the diagnostic procedure with which the diagnostic radiopharmaceutical is used.*** [emphasis added]

The access barrier that CMS describes in relation to the use of diagnostic radiopharmaceuticals – mirrored by the experience with non-opioid pain treatments - is exactly that which ASTCT is trying to avoid in a potential future state for CAR-T and other cellular therapies. Cellular therapy products will continue to vary significantly in terms of price, availability, clinical indication, safety, and outcomes – physicians need to be afforded the full spectrum of choice to meet the best needs of the patient, particularly in situations where only one product addresses the beneficiary's needs or disease or where there are manufacturing capacity constraints.

Finally, CMS' use of C-APCs is not an exception to the ASP+6% payment allowance limit outlined in statute and thus should not be utilized as a mechanism to modify payment for these

therapies; thus, ASTCT asks that CMS continue to follow the payment policy as prescribed by legislation.

ASTCT requests that CMS finalize its proposal to exclude cell and gene therapies with Status Indicator "K" from C-APCs in CY 2025 and beyond, extend the policy to all SI "K" drugs on a permanent basis in the future, and refrain from proposing a C-APC or other bundled payment for CAR-T and other cell and gene therapies.

II. Recognize separate payment for four new CAR-T Category I CPT codes

ASTCT supports CMS' proposed Status Indicator (SI) "S" to the new CAR-T administration CPT code 3X021 (Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous).

In Addendum B of the proposed rule files, CMS assigns SI "B" to three new Category I CPT codes describing clinical services associated with CAR-T:

- 3X018: Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
- 3X019: Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)
- 3X020: Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration

ASTCT disagrees with CMS' assignment of SI "B" for CPT codes 3X018, 3X019 and 3X020 and again requests CMS to recognize separate payment for these distinct clinical services by finalizing SI "S" in the CY 2025 Final Rule.

ASTCT has repeatedly requested that CMS recognize these distinct, provider-furnished clinical services associated with CAR-T therapy, ASTCT requested that CMS provide separate payment for each of the services at the inception of the precursor Category III codes effective January 1, 2019. Collecting a beneficiary's stem cells on an individual with an active blood cancer requires as series of complex and personalized clinical decision-making, along with experienced staff working in specialized clinical settings and using highly technical equipment – this is extraordinarily different from typical pharmaceutical manufacture based on obtaining plant- or chemically-derived base materials. These distinct clinical services are ordered by treating specialists and furnished by hospitals. The services occur during the course of comprehensively treating a beneficiary's illness and take place before and after the manufacturing process – *the manufacturer does not have custody of the patient's cells during the time these services are performed, and the hospitals are fully responsible for the individualized clinical care of the beneficiary*.

As hospitals have gained experience with CAR-T and volume has continued to grow, the need for the modification of CMS' payment policy towards these codes has become acute. Between 10-15% of patients whose cells are collected with the intent of CAR-T manufacture do not receive the product due to clinical status change or manufacturing issues – leaving hospitals completely uncompensated for the clinical services provided. Additionally, hospitals that are

certified to administer CAR-T are exploring partnerships with other hospitals for the cell collection service so that beneficiaries can remain close to home during more of their treatment course. Our understanding is that individual hospitals must bill services furnished to their registered hospital patients occurring at their premises. Other hospitals may furnish these services "under arrangement," with qualified entities to bring necessary equipment, supplies, and trained staff onsite to treat their registered patients. Given the expected growth in these therapies, it is not logical or supportive of beneficiary access to continue the current payment policy for these codes.

HOP Panel recommendations

CMS' Advisory Panel on Hospital Outpatient Payment (HOP) has agreed with ASTCT several times when this issue has been presented. In relation to our request that CMS change the status indicators assigned to the Category III CPT codes, the HOP Panel issued the following recommendation after the August 2018 meeting:

> *The Panel recommends that CMS reassign the status indicators for the following CPT codes from B to S:*
> - *CPT code 05X1T, Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day*
> - *CPT code 05X2T, Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived lymphocytes for transportation (e.g., cryopreservation, storage)*
> - *CPT code 05X3T, Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration*
> - *CPT code 05X4T, Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*
>
> *The Panel further recommends that CMS assign CPT code 05X1T and CPT code 05X4T to APC 5242, Level 2 Blood Product Exchange and Related Services, and CPT code 05X2T and CPT code 05X3T to APC 5241, Level 1 Blood Product Exchange and Related Services.*

CMS provided the following commentary in the CY 2019 OPPS Final Rule in response to the discussion of the HOP Panel recommendation:

> *Response: We do not believe that separate payment under the OPPS is necessary for procedures described by CPT codes 0537T, 0538T, and 0539T. The existing CAR T-cell therapies on the market were approved as biologics and, therefore, provisions of the Medicare statute providing for payment for biologicals apply. The procedures described by CPT codes 0537T, 0538T, and 0539T describe various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. We note that the HCPCS coding for the currently approved CAR T-cell therapy drugs, HCPCS codes Q2040 and Q2041,*

includes leukapheresis and dose preparation procedures because these services are included in the manufacturing of these biologicals.

In subsequent rules, CMS has maintained their statement that "Medicare does not generally pay separately for each step used to manufacture a drug or biological," yet the Agency has not further defined why it views these clinical services as part of the manufacturing process, when they happen before and after a product manufacturer takes ownership of the cells. Furthermore, CMS has not provided further explanation or rationale as to when exceptions to this "general" policy may be made.

During its August 26, 2024, meeting, the HOP Panel once again agreed with ASTCT's request that CAR-T services associated with cell collection and cell processing should be assigned SI "S" and supported our request that these services be assigned to payable APCs. The ASTCT was pleased with the discussion and the recommendation of the Panel as it echoes our understanding that these are clinical services provided by hospitals to patients and are separate from the manufacturing process or from the payment of the drug/biological CAR-T HCPCS Q codes.

New gene therapy HCPCS product codes

ASTCT believes CMS recently changed its perspective about assigning Q codes to biologics that include distinct clinical services in the descriptors of biologics even when the overall episode of care involves cell collection and cell processing. Specifically, we were heartened to see CMS recently grant two J codes for new gene therapies that do not reference the clinical services of cell collection and cell processing in the code's descriptions despite those being as inherent to the treatment process of these gene therapies as cell collection and cell processing are to CAR-T therapies:

- J3394 (Lyfgenia): "Injection, lovotibeglogene autotemcel, per treatment"
- J3393 (Zynteglo): "Injection, betibeglogene autotemcel, per treatment"

These two therapies are utilized by ASTCT members to treat genetic blood disorders and are administered via a stem cell transplant; they are autologous (made from a patient's own cells) products and thus require the same types of cell collection (leukapheresis) and processing by a hospital's cell lab before and after the manufacturing process as CAR-T cells.

ASTCT supports the way that CMS' HCPCS Working Group created these codes, as it reflects a recognition that leukapheresis and cell processing should not be embedded in Level II HCPCS code descriptors when these complex clinical services are already described by unique Level I HCPCS codes with APCs assigned (CPT codes 38206 and 38207-38215, depending on services needed). The exclusion of these clinical services from the J codes allows providers to be compensated for the clinical care they provide to Medicare patients as part of treatment of their disease, entirely separate from the final biologic (i.e. the cell or gene therapy product) that may or may not be administered due to a change in the clinical status of a patient.

Request for revision to CAR-T HCPCS product codes

This decision from the HCPCS Working Group prompted ASTCT to submit code change requests through MEARIS for all six HCPCS Level II CAR-T product Q codes so that the

agency can change these descriptions in time for a January 1, 2025 implementation to match up with the implementation of the new HCPCS Level I CAR-T codes (Category I CPT codes) and to better align with the Health Information Portability and Accountability Act (HIPAA) language governing code sets, as it states that HCPCS Level II is described as *"…a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services* ***not included in the CPT® code set jurisdiction****"*[3] [emphasis added] - as the CAR-T clinical services are now within the jurisdiction of AMA CPT codes, the services described by the codes should be removed from HCPCS product descriptors.

CMS acknowledgement of CAR-T clinical services

ASTCT notes that by CMS seeking input on the Practice Expense values for the cell collection and processing codes (3X018-3X020) in the CY 2025 Medicare Physician Fee Schedule (MPFS) Proposed Rule, CMS further affirms that it views these services as distinct and separate from the drug or biological product, and that they require clinical resources that should be reimbursed. This has been noted by our membership and our collaborative stakeholders, and we look forward to CMS finalizing proposed work and physician expense values for the new codes. Given these indicators by the agency that CMS recognizes the distinct clinical services associated with cell and gene therapy clinical care episodes, ASTCT was surprised by CMS proposing SI "B" for the new CAR-T Category I CPT codes and assumes this may be either be an erroneous carryover from the prior codes or the product of a timing issue between when the rule was being reviewed and when the HCPCS Working Group released its final J codes, as there was no discussion of the situations may be similar or different in the OPPS proposed rule text. Since ASTCT members furnish both cell and gene therapies, we ask that CMS make consistent policies for payment and billing of the clinical services.

New Category I CPT codes create an opportunity for resolution of the issue

The conversion of the existing CAR-T Category III CPT codes to Category I for implementation January 1, 2025, creates an optimal opportunity for CMS to do two things: one, make a change in the HCPCS Level II CAR-T product Q code descriptions as described above and two, make a change in its corresponding payment policies by assigning SI "S" and payable APCs. If CMS' HCPCS Working Group accepts ASTCT's requested modification of the CAR-T product Q codes so that new descriptors are finalized and implemented January 1, 2025, then the CAR-T codes will mirror what CMS has done for gene therapies and the discrepancies between the way the two groups of therapies will be resolved. ASTCT appreciates that CMS has evolved its perspective as it gains more experience with cell and gene therapies and how much they differ from the manufacturing steps required to produce off-the-shelf drugs that utilize typical materials.

ASTCT requests that CMS finalize the SI "S" assignment and placement of 3X021 in APC 5694 for CY 2025 and change the proposed assignment of "B" to "S" for CPT codes 3X018, 3X019,

[3] CMS, *Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures*, Baltimore (MD): CMS, December 2022, pg. 1. Online: https://www.cms.gov/medicare/ coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf

and 3X020. CMS should finalize assignment of CPT code 3X018 to APC 5242 and CPT codes 3X019 and 3X020 APC 5241.

III. Additional OPPS proposals

Market Basket Adjustment

In this year's FY 2025 OPPS proposed rule, CMS is proposing a net 2.6% increase to the market basket (increase of 3.0% with a productivity adjustment -0.4%). The 2.6% proposed increase will not offset the inflation and increased costs for labor, supplies and drugs that hospitals are experiencing. **ASTCT asks that CMS reconsider its proposed market basket increase to no less than the 3.4% it finalized in the FY2025 IPPS Final Rule.**

Non-Opioid Treatments for Pain Relief

ASTCT supports CMS' proposal to provide separate payment for non-opioid treatments for pain. Our patients may experience significant and chronic pain as a side effect to the treatment of their blood cancers or disorders and could be at an increased risk for substance use disorders. Therefore, a policy that allows separate payment for treatments will enable hospitals to provide the best care to their patients without facing financial pressures. **ASTCT encourages CMS to finalize its proposals to provide separate payment for the seven drugs and the one device identified in the Proposed Rule.**

Diagnostic Radiopharmaceuticals

ASTCT supports the unpackaging of diagnostic radiopharmaceuticals. We appreciate the agency's discussion of solicited stakeholder feedback and acknowledgement that patients may not get the therapies they need because of CMS' underestimation of procedure payment due to issues with charge compression, among other calculations. As such, unpackaging the products will support hospital decision-making around the best products to use with the associated procedure(s) patients need without introducing financial pressures outside of the hospital and patient's control. **ASTCT requests that CMS finalize its proposal to unpackage diagnostic radiopharmaceuticals.**

Add-on Payment for Domestically Produced Technetium-99m (Tc-99m)

CMS proposes to provide a new add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced molybdenum-99 (Mo-99) in CY 2026. **ASTCT recommends the agency finalize this policy for CY 2026.**

Extension of Virtual Direct Supervision of Rehabilitation and Diagnostic Services

CMS has proposed an extension of direct supervision via audio-video real-time communications technology through December 31, 2025, for cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, and diagnostic services. ASTCT supports any and all efforts by CMS to extend virtual and/or remote flexibilities due to the immunocompromised state of many patients after receiving stem cell transplants and/or other cellular or gene therapies.

Many patients live substantial distances from the specialized centers at which they receive care, so having access to virtual options concurrently support patient rehabilitation and caregivers in returning to work or other daily responsibilities. **ASTCT requests that CMS finalize this proposal for CY 2025 and work with Congress to preserve these options to support beneficiaries in the future.**

Caregiver Training Services

Hospitals require the availability of a dedicated caregiver for a patient to receive a stem cell transplant or other cellular or gene therapy due to an extended recovery period and complex healthcare needs during that period. Having a knowledgeable caregiver is critical to the success of the treatment.

As such, ASTCT is very appreciative that CMS recognized the importance of Caregiver Training Services (CTS) as well as Principal Illness Navigation (PIN), Social Determinants of Health (SDOH) assessment, and Community Health Integration (CHI) by providing payment beginning in 2024.

CMS' assignment of value to CTS in the CY 2024 MPFS Final Rule (codes 97550-97553) allows physicians, non-physician practitioners, and therapists to bill for the provision of these services, which ASTCT appreciates. However, ASTCT notes that once the treating clinician outlines a course of treatment for the patient and evaluates caregiver knowledge, it is likely to be qualified and employed auxiliary team members that provide the CTS services directly to the caregiver. CPT codes 97550-97553 have an OPPS status indicator "A," indicating that MPFS payment to outpatient hospitals is applicable when therapists furnish CTS but is not applicable to nurses or other trained auxiliary personnel who follow clinician orders to conduct caregiver training under in a hospital outpatient setting.

Therefore, ASTCT was encouraged by CMS' proposal for new CTS codes GCTD1, GCTD2 and GCTD3 CTS services for facility and non-facility settings. ASTCT asks that CMS clarify whether these codes will also be restricted to physicians, non-physician practitioners and therapists like the 97550-97553 codes. We were encouraged because these code descriptors are particularly well suited to the work qualified and employed auxiliary team members provide to caregivers under treating clinician orders. ASTCT asks CMS to finalize a payment policy that allows for additional staff members and types (such as certified oncology nurses) to bill for these services. We noted that GCTD1-GCDT3 are not listed within the Addendum B file issued with the release of the OPPS CY 2025 Proposed Rule, so we are unable to determine which team members would be able to bill and be paid for these services.

ASTCT requests that CMS make the newly proposed CTS HCPCS codes GCTD1-GCTD3 payable under OPPS.

Medicaid and CHIP Continuous Eligibility

ASTCT supports CMS' proposal to require 12 months of continuous eligibility for children under the age of 19 who are enrolled in Medicaid and CHIP and concurrently supports removal of failure to pay premiums as an optional exception to continuous eligibility. ASTCT members

frequently treat children and young adults for blood cancers and disorders, which often requires lengthy and complex treatments like stem cell transplant. Maintaining a level of continuous eligibility ensures that these patients will not lose coverage mid-treatment or during the immediate post-intervention treatment, when monitoring and supportive therapies are incredibly important to the success of the primary therapy.

ASTCT asks CMS to finalize its proposal and consider future extensions of this policy for patients undergoing active treatment for cancer, blood disorders or other grave illnesses requiring stem cell transplantation, cellular therapy and/or gene therapy.

ASTCT thanks CMS for the opportunity to comment on the CY 2025 OPPS proposed rule.