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: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (MPFS) 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 that advance the science of cellular therapy, including participation in trials that lead to current Food and Drugs Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

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 CAR-T therapies and other therapies to treat blood cancers and solid tumors, due to the specialized expertise required to safely administer these products in the clinical setting. Additionally, ASTCT members are at the forefront of using genetically edited hematopoietic stem cells for the treatment of 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 has highlighted challenges within the Medicare coverage, coding, and payment systems. ASTCT remains concerned about the potential barriers to care that these challenges 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.

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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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Table of Contents

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Valuation of Category I CPT codes for CAR-T Services

CAR-T therapy is a type of immune effector cell therapy utilized by ASTCT members to treat certain hematologic malignancies. In succession to the precursor Category III CPT® codes implemented in 2019, four new Category I CPT® codes for CAR-T clinical services will become effective as of January 1, 2025:

- 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.
- 3X021 Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous.

CMS discusses the new codes and its proposed valuation of the services in the following section of the Proposed Rule:

> *In September 2023, the CPT® Editorial Panel deleted four category III codes (0537T–0540T) and approved the addition of four new codes (3X018– 3X021) that describe only steps of the complex CAR–T Therapy process performed and supervised by physicians. The RUC recommended four different work RVUs for codes 3X018, 3X019, 3X020, and 3X021 and only recommended direct PE values for code 3X021. For CPT® code 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) the RUC recommended a work RVU of 1.94. For CPT® code 3X019 (Chimeric antigen receptor T-cell (CAR– T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)) the RUC recommended a work RVU of 0.79. For CPT® code 3X021 (Chimeric antigen receptor T-cell (CAR–T) therapy; CAR– T cell administration, autologous) the RUC recommended a work RVU of 3.00. For CPT® code 3X020 (Chimeric antigen receptor T-cell (CAR–T) therapy; receipt and preparation of CAR–T cells for administration) the RUC recommended a work RVU of 0.80 and for CPT® code 3X020, we are proposing the RUC recommended work RVU of 0.80.*
>
> *We are proposing the RUC-recommended work RVUs for CPT® codes 3X018, 3X019, and 3X021 respectively. As mentioned previously, the RUC recommended direct PE values for only one code, CPT® code 3X021, and the RUC recommended that the non-facility PE RVU for CPT® codes 3X018–3X020 should be contractor-priced. However, contractor pricing can only be applied at the whole code level, not to a single component of the valuation. Therefore, for CPT® codes 3X018–3X020 we are treating these codes as having no recommended direct PE values and are seeking comment on direct PE values*

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for these codes. We are proposing the RUC recommended direct PE inputs for CPT® code 3X021.

ASTCT appreciates the discussion of these new codes and is grateful to have the opportunity to provide input on it. CAR-T therapy involves multiple steps over an extended timeline (e.g., weeks to months in duration) and substantial resources to support specialized, multidisciplinary care delivery. This endeavor requires a significant investment in training, staff, and clinical resources. In addition to CAR-T being provided to hospital inpatients and hospital outpatients, CMS must acknowledge that CAR-T is used in non-facility settings (i.e., physician offices) via the billing instructions issued in 2022 as part of *Transmittal 11774*.[1]

ASTCT agrees with CMS' proposal to recognize the resources required to provide this therapy by finalizing the RUC recommended work values for all four CPT® codes and the direct practice expense (PE) inputs for CPT® code 3X021.

In addition, ASTCT recommends that CMS review stakeholder comments and data for the direct PE values for CPT® codes 3X018-3X020 and assign appropriate non facility practice expense RVUs. This is an important interim measure that will ensure beneficiary access to care in all valid places of service until these services are re-reviewed through the typical AMA process for new technology services.

In summary, ASTCT requests that CMS:

- **Finalize the work RVU recommendations from the RUC for CPT® codes 3X018-3X021;**
- **Finalize the PE RVU for CPT® code 3X021; and**
- **Finalize PE inputs submitted by clinically relevant stakeholders for CPT® codes 3X018-3X020.**

Modification of CAR-T Product Q codes

Related to the prior topic, **ASTCT requests that CMS engage with the HCPCS Working Group to approve ASTCT's requested changes to the current CAR-T HCPCS product codes—namely, the elimination of clinical services ("leukapheresis and dose preparation procedures") from all product descriptions.** Given the implementation of the new AMA Category I CPT® codes for CAR-T that will become effective on January 1, 2025, the inclusion of these distinct clinical services in the product HCPCS descriptions is duplicative and confusing to providers.

[1] CMS Pub 100-04 Medicare Claims Processing. Transmittal 11774, Change Request 12928 (2002)

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Conversion Factor Update

CMS proposes a 2.8% decrease for CY 2025. ASTCT opposes this decrease in payment, which would add to already significant financial strains for physicians who are attempting to deal with the effects of increased inflation. ASTCT understands that CMS is bound by the statute relating to the MPFS conversion factors, which has unintentionally led to ongoing annual reductions. If CMS wishes to preserve provider access for Medicare beneficiaries, however, the agency needs to collaborate with Congress to modify legislation and develop a sustainable solution.

ASTCT asks CMS to engage the leadership of the U.S. Senate Finance Committee and the House of Representatives' Ways and Means Committee to identify and implement a solution to support beneficiary access.

Telehealth and Other Communications Technology Services

ASTCT greatly appreciates the extent to which CMS was able to use its Public Health Emergency authority to extend and augment the availability of telehealth and similar services for Medicare beneficiaries over the past several years. We understand that CMS' authority will sunset at the end of 2024 unless Congress acts to extend the legislation.

We appreciate that CMS proposed telehealth extensions for several services for CY 2025. **ASTCT encourages CMS to finalize these proposals, particularly the ability to use audio-only options when necessary and to allow clinicians to use their enrolled practice locations instead of their home address.**

However, we also wish to provide feedback on CMS' comments regarding the expiration:

> *We recognize that there are significant concerns about maintaining access to care through the use of Medicare telehealth services with the expiration of the statutory flexibilities that were successively extended by legislation following the PHE for COVID–19. We understand that millions of Medicare beneficiaries have utilized interactive communications technology for visits with practitioners for a broad range of health care needs for almost 5 years. We are seeking comment from interested parties on our understanding of the applicability of section 1834(m) of the Act to the new telemedicine E/M codes, and how we might potentially mitigate negative impact from the expiring telehealth flexibilities, preserve some access, and assess the magnitude of potential reductions in access and utilization.*
>
> *…However, we are unsure of the continuing validity of that premise under the current circumstances where patients have grown accustomed over several years to broad access to services via telehealth. We are seeking comment on what impact, if any, the expiration of the current flexibilities would be expected to have on overall service utilization for CY 2025. [p. 61654]*

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ASTCT wishes to emphasize that not only have beneficiaries "grown accustomed" to this access, but also that these access options have a direct positive impact on the health and well-being of beneficiaries and their caregivers. The clinical services that ASTCT members provide (e.g., stem cell transplantation, stem-cell-based gene therapies, and cellular therapies like CAR-T) are highly specialized services provided at limited locations. Patients usually travel long distances to receive these therapies, and frequently need to temporarily relocate during the extensive course of treatment. The availability of telehealth and other communication services has greatly increased access to specialist teams for purposes of post-treatment concerns and monitoring once beneficiaries are back at their homes. Our members have also noted that the availability of virtual options decreases infection risk to patients (who are significantly immunocompromised after treatment) and supports caregivers in returning to work and/or other commitments.

The expiration of most telehealth services will have detrimental effects on the patient population we serve. It may mean that some patients face challenges in obtaining the care they need from providers with the specialized expertise necessary to treat them appropriately. It will likely increase financial burden and toxicity, as patients and caregivers need to resume frequent travel far from their homes, typically on limited incomes.

ASTCT asks CMS to consider ways to use its authority to extend the flexibilities the agency has implemented to allow patients who have received a stem cell transplant, cellular therapy, or gene therapy to continue using telehealth services. This is necessary to ensure that they can access the appropriate expertise in a manner that does not compromise their health.

Defining Complex Non-Chemo Drugs through Subregulatory Guidance

Many providers have questions about the variations in how Medicare Administrative Contractors (MACs) pay for drug administration services billed for complex non-chemotherapy drugs. As a result, CMS proposes to release additional sub-regulatory guidance that is intended to be consistent with the AMA CPT® guidelines:

> *"96401-96549 are differentiated from the non-chemo/non-complex hydration and therapy codes because codes 96401-96549 require more staff monitoring for reactions, adverse events, and extra staff training compared to what is involved with hydration or non-chemo injection and infusion services.*"

ASTCT believes that CMS' subregulatory guidance should (a) result in consistent determinations by all MACs, and (b) adhere to the AMA CPT® criteria, which would confirm correct coding and payment of drug administration services for complex non-chemotherapy drugs.

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Our membership is also concerned that CMS' guidance follows AMA CPT® coding of stem cell and CAR-T administration—which are distinctly different from complex non-chemotherapy drugs and have unique Category I CPT® codes. AMA CPT® has determined that the administration of cell therapies should not be billed with the complex drug administration codes. It has established specific CPT® codes (i.e., 38240, 38241, 3X021) that recognize the clinician work required for safe and effective administration of these therapies, which contrasts with the complex drug administration CPT® codes that are not allowed for clinician billing in facility settings under MPFS.

ASTCT requests that CMS update the current Internet Only Manual (IOM) to include the AMA CPT® criteria for MACs to reference, to ensure that providers experience consistent coverage and payment for these services. ASTCT also requests that CMS clarify that stem cell transplant and CAR-T services should not be billed with the complex drug administration codes in the IOM, since specific Category I CPT® codes exist for these services.

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. This is necessary because of the extended recovery period and complex health care needs the patient experiences during that time. In short, 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) 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. Yet, ASTCT notes that, once the treating clinician outlines a course of treatment for the patient and evaluates caregiver knowledge, it is likely that qualified and employed auxiliary team members are the ones who provide 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 for facility and non-facility settings. ASTCT asks CMS to clarify whether these codes will also be restricted to physicians, non-physician practitioners, and therapists (like the 97550-97553 codes). We are encouraged because these code descriptors are particularly well-suited to the work that qualified and employed auxiliary team members provide to caregivers under treating clinician orders.

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ASTCT asks CMS to make the newly proposed CTS HCPCS codes GCTD1-GCTD3 payable when services are furnished by auxiliary staff "incident to" a clinician's service in the non-facility setting and under orders in the facility setting.

Hospital Inpatient or Observation E/M Add-On for Infectious Diseases

CMS proposes a new HCPCS add-on code for intensity and complexity of inpatient or observation care associated with a confirmed/suspected infectious disease performed by a physician who has specialized training in infectious diseases. Patients undergoing stem cell transplant, gene therapy, and cellular therapies are frequently immunocompromised and immunosuppressed during their treatment, making infectious disease a significant (and potentially fatal) concern. The services that ASTCT members provide are administered with the assistance of a multidisciplinary team of specialists, including those with infectious disease expertise. **ASTCT appreciates CMS' proposal and asks the agency to finalize add-on payment for infectious disease specialists, as proposed, with add-on code GIDXX.**

Compounded Immunosuppressive Drugs

In the proposed rule, CMS notes that certain patient groups may need to rely on compounded versions of immunosuppressive drugs, versus those that have been approved for marketing by the FDA. This conflicts with the requirements CMS established in relation to the immunosuppressive drug benefit. In the rule, CMS proposes the following:

> *Therefore, we are proposing revisions at § 410.30 to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs where approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue, or have been determined by a MAC, in processing a Medicare claim, to be reasonable and necessary for this specific purpose as outlined in the immunosuppressive drug benefit. [61776]*

ASTCT enthusiastically supports this revision and expansion but asks that CMS explicitly confirm that stem cell transplant patients are included in CMS' "transplanted organ or tissue" language.

G2211 Complexity Add-On Code

CMS proposes to allow HCPCS add-on code G2211 to be billed in conjunction with an E/M visit code for an annual wellness visit, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting. We appreciate CMS' recognition that these visits are appropriate for billing the add-on code. **ASTCT supports this proposal and requests that CMS finalize this policy change as proposed.**

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The ASTCT notes that CMS has publicly announced its intent to publish Frequently Asked Questions (FAQs) and other guidance for this add-on code to clarify its use and supporting documentation. Treating oncologists would qualify to report this code when they serve as the focal point for treating cancer patients. ASTCT would, however, appreciate more clarity regarding appropriate reporting of this code for additional payment. **The ASTCT asks CMS to publish additional guidance regarding reporting G2211 no later than publication of the Final Rule.**

ASTCT thanks CMS for the opportunity to comment. Please contact Alycia Maloney, ASTCT's Director of Government Relations, at *amaloney@astct.org*, for any further questions or to discuss these issues.

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