ASTCT®
American Society for
Transplantation and Cellular Therapy

This document contains submitted ASTCT comments and CMS responses from the CMS OPPS Final Rule[1], dated November 1, 2024.

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

September 6, 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 that 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 of using genetically edited hematopoietic stem cells for the

[1] This document is scheduled to be published in the Federal Register on 11/24/2024 and is available online at http://federalregister.gov/d/2024-25521 and on http://govinfo.gov

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 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 the Centers for Medicare & Medicaid Services (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 key 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 American Medical Association (AMA) Current Procedural Technology (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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I. 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. We encourage 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[ing] possible complications" of another procedure, as discussed on page 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. It will enable them to avoid 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.

CMS Responses: (pp.74-75)

Comment: *Commenters were generally very supportive of the proposal and thought this agency action was a positive step forward to ensure access to these new classes of drugs. They agreed with CMS's assessment that the cell and gene therapies listed in the CY 2025 OPPS/ASC proposed rule did not function as integral, ancillary, supportive, dependent, or adjunctive to any of the current C-APCs primary services. Commenters noted that they agreed that these treatments acted as independent therapies and were the reason for a Medicare beneficiary's visit to a hospital outpatient department. Additionally, commenters believed that this policy was necessary and important given the large number of cell and gene therapy products currently being researched that may ultimately be approved and available to Medicare beneficiaries in the coming years.*

Response: *We thank commenters for their support of our proposal and rationale.*

Comment*: Many commenters recommended CMS make this policy permanent as soon as possible. They noted that they agreed with CMS's assessment that it would be inappropriate to package cell and gene therapies into C-APCs for CY 2025 only, but that the same reasons that CAPC packaging would be inappropriate for CY 2025 would also apply to subsequent years.*

Response: *We thank commenters for their feedback.* ***Based on the comments received, we are persuaded that the reasoning for excluding these cell and gene therapy products from CAPC packaging in CY 2025 would also apply to subsequent years. As such, we will be finalizing our proposal as later discussed in this section for CY 2025 and subsequent years*** [emphasis added]. (p. 75)

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.*[2]

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.

We recognize the concept of packaging under OPPS. Yet, we believe it is inappropriate 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. These products 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 will result 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. 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 show, 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—the simplest policy 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. This

[2] CMS APC Panel Archives

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: to exclude the cell and gene therapies in Table 1 from packaging into any C-APC. We also 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.

CMS Responses: (pp. 75-78)

Comment: *Some commenters recommended that CMS extend the proposed policy to cell and gene therapies assigned to status indicator "G", which correlates to pass-through status…A few commenters suggested CMS should review and identify any other products that may be administered as independent therapies in the hospital outpatient setting and stated that such products should be separately paid.*

Response: *We greatly thank commenters for their detailed comments.* ***For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C-APC primary service that were approved during CY 2024 and that continue to be approved, CMS will add their product specific HCPCS codes, when created, to the C-APC exclusion list*** [emphasis added]. (p. 75)

We also thank commenters for their suggestions to add additional drugs and classes of drugs to this C-APC exclusion policy as well as those drugs that are administered during a C-APC procedure… We believe that cell and gene therapies are a unique class of products, but ***we believe we need additional evidence and engagement from interested parties concerning whether other identified classes of drugs, biologicals, medical devices, or other products are not supportive of a primary C-APC service but may nonetheless appear on the same claim as a primary C-APC procedure*** [emphasis added]. (p.76)

In response to commenters suggestion that we apply this policy to cell and gene therapy products assigned to status indicator "G", ***we note that we specifically did not propose to include therapies that are on drug pass-through status, represented by status indicator "G" for all of CY 2025 because pass-through drugs are already excluded from C-APC packaging.*** *Please see section V.A of this final rule with comment period for additional information on OPPS drug pass-through status* [emphasis added]. (p. 77)

Comment: *Several commenters recommended that CMS unpackage all status indicator "K" drugs from C-APC packaging, which aligned with the 2024 Advisory Panel on Hospital Outpatient Payment recommendation to no longer package drugs with a status indicator of "K" into any C-APC and, instead, they recommended CMS provide separate payment for all drugs and biologicals above the drug packaging threshold. Commenters said these status indicator "K" drugs should be paid based on 1847A of the Social Security Act and reimbursed at Average Sales Price plus 6 percent rather than packaged. Commenters suggested that the proportion of status indicator "K" drug charges relative to all other charges appearing on C-APCs claims*

was less than 2.5 percent across all C-APCs. Meaning, in commenters' views, that C-APCs do not inherently involve the provision of status indicator "K" drugs.

Response: *We appreciate the information submitted by commenters, but respectfully disagree with their conclusions... We believe it is appropriate for most drugs and biologicals to be packaged into C-APCs as we believe they function to "promote a beneficial outcome" or "prevent possible complications" of C-APC services.* ***We are therefore not excluding all status indicator "K" drugs above the drug packaging threshold from C-APC packaging*** [emphasis added]. *Our packaging policies are a fundamental component of the OPPS and they support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. Additionally, we do not believe at this time that cost alone is a reason to exclude a product from packaging.* (p. 78)

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.

Response: *We thank commenters for their feedback.* ***Based on the comments received, we are persuaded that the reasoning for excluding these cell and gene therapy products from CAPC packaging in CY 2025 would also apply to subsequent years. As such, we will be finalizing our proposal as later discussed in this section for CY 2025 and subsequent years*** [emphasis added]. (p. 75)

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

For several clinical and operational reasons, 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.

The clinical processes associated with CAR-T are spread out over weeks to months and include clinical evaluation, cell collection, receipt of product from the manufacturer, and lymphodepletion of the patient. These processes are driven by the 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 in order to temporarily decrease disease burden while a CAR-T product is being manufactured (i.e., use of a "bridging" therapy or regimen). It would be highly problematic if these therapies and other clinical services were inappropriately swept into a C-APC where a single payment is typically made.

If CMS implements 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 its 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, in situations where 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 the multiple entities that could provide them, creating a single "episodic" C-APC payment that attempts to encompass all aspects of the care process—even on average—is unnecessarily complex. Doing so will almost certainly result in placing undue administrative, operational, and financial burden on hospitals, which ASTCT cannot support. Furthermore, the claims data are likely to be fraught with errors, given the unprecedented nature of such a C-APC.

For example, if CMS created an episodic C-APC that included HCPCS codes that 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 its typical process for submitting 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; they 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. Doing so fosters easier and faster claims processing and enables hospitals to be paid in a timely and appropriate fashion.

It is unnecessarily complex and burdensome for CMS deviate from its standard and implement some form of episodic claims preparation (or reprocessing of claims, etc.) to support C-APC payment, where it is inappropriate. There is no need for the agency to do this, given 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 never 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. In fact, it would be extremely burdensome for providers to identify, hold, and finally aggregate "all related services" on a single claim. 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;[3] to further extend that places a unique burden on providers that offer this service compared to other drugs and treatments.

ASTCT has a related recommendation: to assign SI "S" to CPT codes 3X018, 3X019, and 3X020. This change would enable CMS to eliminate the complex billing requirements and pay providers for the clinical services they provide (as described in the following section); it would be a welcome relief to the existing confusion and burden providers experience today. We also note that such an episodic C-APC would create unnecessary complexities for CMS to ensure even a modicum of reasonable payment.

Finally, in other sections of the Proposed Rule, CMS discusses two situations where prior packaging decisions have had detrimental impacts on access and where CMS proposes to modify prior policy: diagnostic radiopharmaceuticals and non-opioid pain management. We believe that, 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***

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

> ***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 with respect to diagnostic radiopharmaceuticals (which mirrors the experience with non-opioid pain treatments) is exactly the one that ASTCT seeks to avoid 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. As a result, physicians must have the full spectrum of choice to meet the patient's best needs, 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. For these reasons ASTCT asks CMS to 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.

CMS Response: (p.80)

Comment: *Many commenters responded to several of our requests for comment associated with the proposal. Commenters recommended no significant overall changes to the general methodology CMS proposed to exclude products from all C-APC packaging and pay separately based on the individual product's average sales price plus 6 percent. Specifically, commenters strongly conveyed that they did not see an appropriate reason for CMS to structure a new C*

APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such as by creating a CAR T-cell therapy administration C-APC.

Commenters believed that there is no accurate way to create a bundled payment for a whole group of cell and gene therapies as the costs and resources required are unique and novel between each of the therapies, which also makes it difficult to determine appropriate items and services associated with each therapy for inclusion in C-APC packaging. Commenters broadly believed no different or supplemental policy was warranted given the numerous challenges providers face related to cell and gene therapies currently. They saw any additional change to move towards a packaged payment policy as an additional challenge for the hospitals providing the therapies.

Similarly, commenters cautioned CMS against creating C-APCs for cell and gene therapies as this may cause inadequate Medicare reimbursement to hospitals, which, in their view, has the potential to jeopardize beneficiary access to CAR T-cell therapy and other highcost therapies as commenters communicated that institutions weigh reimbursement challenges with their ability to provide this costly care. Commenters were concerned that creating a new packaged payment policy could lead to a financial loss and decrease the number of facilities offering high-cost cell and gene therapies in the hospital outpatient department.

Commenters emphasized that these therapies involve highly specialized procedures, intensive monitoring, and multidisciplinary care teams, all of which contribute to their substantial costs. Commenters were concerned by the fact that the administration of cell and gene therapies are multi-step processes that can take weeks if not months and entail multiple services that would not appear on the same claim. Additional commenters reiterated that all of the various and distinct clinical services for CAR T-cell therapy are furnished over multiple encounters on different dates—making CAR T-cell therapy inappropriate for C-APCs, which are typically specific to a single encounter in their view. Commenters believed a CAR T-cell therapy C-APC, or similar packaged payment policy, would be unprecedented and a huge policy departure for CMS and recommended CMS not pursue the idea any further.

Many commenters believed that separate payment based on average sales price plus 6 percent is the most appropriate payment methodology for cell and gene therapies due to its transparency, uniformity and predictability. A few commenters pointed out that current hospital cost data is lower than ASP for CAR T-cell therapy products, potentially leaving products underpaid if paid based on C-APC principles. Commenters similarly took the position that there is no appropriate method in which CMS could modify its outlier payment policy with respect toC-APCs to better pay for these types of products.

Response:** We appreciate the insights provided by commenters and will take them into consideration for future rulemaking. **At this time, we are not considering the creation of a new C-APC, similar packaged payment policy, or modified outlier policy, for services to administer cell or gene therapies [emphasis added].

CMS Response Summary (p. 81)

After consideration of the public comments we received, we are finalizing our policy proposal with a modification with respect to how long this policy will apply. For CY 2025 and subsequent years, we are finalizing a policy not to 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. For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any CAPC primary service, we will continue to add their product specific HCPCS codes, when created, to the C-APC exclusion list. ***The current list of qualifying products can be found in Table 4.*** *We are not adding any additional drug classes to this policy exclusion at this time, and we are not currently considering any additional modifications to our policy, but will continue to consider additional refinements for future rulemaking. We list all final C-APC exclusion categories for CY 2025 in Addendum J to this fina lrule (which is available via the Internet on the CMS website at https://www.cms.gov/medicare/payment/prospective-paymentsystems/hospitaloutpatient/regulations-notices).*

TABLE 4: CELL AND GENE THERAPIES FINALIZED FOR EXCLUSION FROM CAPC PACKAGING FOR CY 2025

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Carvytki	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment

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

ASTCT supports CMS' proposal to assign SI "S" to the new CAR-T administration CPT® code 3X021 (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; we again request 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 that became effective January 1, 2019. Collecting a beneficiary's stem cells on an individual with an active blood cancer requires a series of complex and personalized clinical decision-making, along with experienced staff working in specialized clinical settings and using highly technical equipment. This process is significantly different from typical pharmaceutical manufacturing 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 grown, the need for CMS to modify its payment policy for 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. When this happens, hospitals are completely uncompensated for the clinical services already provided. Additionally, hospitals that are certified to administer CAR-T are exploring partnerships with other facilities for cell collection service so 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.

CMS Response: (p.378-380)

Comment: *Several commenters opposed our proposal to continue to assign status indicator ''B'' to CPT codes 38225, 38226, and 38227, for CY 2025. Many commenters provided alternate status indicator assignment recommendations, such as "S", as well as APC assignment recommendations. Commenters stated that by allowing these codes to be billable and paid, CMS could use claims data collected to assign the codes to more accurate APCs*

Response: *We thank the commenters for their feedback. CMS continues to believe that the procedures described by CPT codes 0537T, 0538T, and 0539T and replacement CPT codes 38225, 38226, and 38227, describe the 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 product. Therefore, CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 38225, 38226, and 38227, for CY 2025.*** *However, we thank commenters for providing their unique perspectives and experiences in situations where the manufacturing process does not result in a final product being administered to a beneficiary* [emphaisis added]. (p. 378-379)

Additional Comment*: Some commenters explained that CMS's overall practice and billing process should be reevaluated, with some recommending revisions to, or the retirement of, MLN Matters Number SE1900926 which they believed caused confusion, raised numerous program integrity concerns, including confusion regarding what can be included in ASP reporting, increased inconsistencies with Medicare requirements for under arrangement services and with charges reported and hospital billing, and commenters believed the elimination of this guidance, including separate payment of 38225, 38226, and 38227, would reduce hospital burden.*

Response: *We thank commenters for their feedback and for raising concerns related to our guidance contained in MLN Matters Article SE19009.* ***We are not revising this document at this time as we believe these instructions are consistent with our longstanding policies, but we understand the feedback provided*** [emphaisis added]. (p. 379-380)

HOP Panel recommendations

CMS' HOP Panel has agreed with ASTCT several times when this issue has been presented. In relation to our request that CMS change the SIs 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 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 its statement that "*Medicare does not generally pay separately for each step used to manufacture a drug or biological*." Yet, the agency has never 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 Panel's recommendation, which 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.

CMS Response: (p.378)

Comments: *Commenters supported the 2024 Advisory Panel on Hospital Outpatient Payment recommendation to assign CPT code 38225/3X018, Chimeric antigen receptor T-cell therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day, an SI of S and place the code in APC 5242, Level 2 Blood Product Exchange and Related Services. The Panel further recommended that CMS assign CPT code 38226/3X019, Chimeric antigen receptor T-cell therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage); and CPT code 38227/3X020, Chimeric antigen receptor T-cell therapy; receipt and preparation of CAR-T cells for administration; an SI of S and place these codes in APC 5241, Level 1 Blood Product Exchange and Related Services.*

Response: *We thank the commenters for their feedback.* ***CMS continues to believe that the procedures described by CPT codes 0537T, 0538T, and 0539T and replacement CPT codes 38225, 38226, and 38227, describe the 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 product. Therefore, CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 38225, 38226, and 38227, for CY 2025.***

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 that CMS recently granted 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 these gene therapies' treatment process as cell collection and cell processing are to CAR-T. These codes are:

- 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 (e.g., 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 do CAR-T cells.

ASTCT supports the way that CMS' HCPCS Working Group created these codes. 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 disease treatment, 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.

CMS response: see text in following CAR-T HCPCS product codes section

Request for revision to CAR-T HCPCS product codes

This HCPCS Working Group's decision prompted ASTCT to submit code change requests through MEARIS for all six HCPCS Level II CAR-T product Q codes. Implementing these changes will enable the agency to change these descriptions in time for a January 1, 2025 implementation, to match implementation of the new HCPCS Level I CAR-T codes (Category I CPT codes). It will also better align with the Health Insurance Portability and Accountability Act (HIPAA) language governing code sets, which describes HCPCS Level II 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****"*[4] [emphasis added]. Given that 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 Response: (p.378-379)

Comment: *Commenters also recommended CMS revise the product specific Q-codes to remove "leukapheresis and dose preparation procedures" and they believe it is inappropriate for these services to be described by the HCPCS Level II codes when they can be described by Level I HCPCS codes. Additional commenters recommended CMS transition the product specific Q-codes to permanent J-codes. Several commenters discussed other therapies, such as stem cell transplant, and therapies such as those described by HCPCS codes J3394 (Injection, lovotibeglogene autotemcel, per treatment) and J3393 (Injection, betibeglogene autotemcel, per*

[4] 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

treatment), which in commenter's view is similar to CAR T-cell therapy and requires similar dose preparation procedures.

Response: *We note that* ***the current HCPCS coding for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures, as these services are included in the manufacturing of these biologicals. Therefore, payment for these services is incorporated into the drug codes****. CMS is not revising the descriptors for the Q-codes to remove leukapheresis and dose preparation procedures nor are we transitioning the Q-codes to J-codes at this time.*

CMS acknowledgement of CAR-T clinical services

In the CY 2025 Medicare Physician Fee Schedule (MPFS) Proposed Rule, CMS seeks input on the practice expense values for the cell collection and processing codes (3X018-3X020). ASTCT notes that, by doing so, 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 practice expense values for the new codes.

Yet, given the agency's recognition of the distinct clinical services associated with cell and gene therapy clinical care episodes, ASTCT was surprised that CMS proposes SI "B" for the new CAR-T Category I CPT® codes. We assume this is either an erroneous carryover from the prior codes, or a timing issue stemming from the period between when the rule was being reviewed and when the HCPCS Working Group released its final J codes. CMS has not included any discussion of how these 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.

CMS Response: (p.376)

Comment: *Some commenters provided input on the proposed policies in the physician office setting regarding the dose preparation procedures associated with CAR T-cell therapy and other billing topics in the office setting...*

Response: *Comments related to the CY 2025 PFS payment policies are out of scope.*

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 necessary things. First, CMS should change the HCPCS Level II CAR-T product Q-code descriptions (as described above) and

second, CMS should change 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. The discrepancies between the way the two groups of therapies are treated will be resolved. ASTCT appreciates that CMS' perspective has evolved as the agency gains more experience with cell and gene therapies and how much they differ from the manufacturing steps required to produce off-the-shelf drugs.

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

CMS Response: (p. 379-380)

Response: [W]e are not accepting the recommendations at this time to revise the status indicators for procedures described by CPT codes 38225, 38226, and 38227. We will continue to evaluate and monitor payment for CAR T-cell therapies. *In summary, after consideration of the public comments we received,* ***we are finalizing our proposal to assign status indicator ''B'' to CPT codes 38225, 38226, and 38227 for CY 2025 without modification. Additionally, we are continuing our policy from CY 2019 to assign status indicator ''S'' to CPT code 38228 for CY 2025.*** *Table 81 shows the final SI and APC assignments for HCPCS codes 38225, 38226, 38227, and 38228 for CY 2025. For more information on CY 2025 OPPS final status indicators, APC assignments, and payment rates for HCPCS codes, including the CAR T-cell drug codes, we refer readers to Addendum B to this final rule with comment period. In addition, the status indicator definitions can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2025) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.*

(Please see next page for Table 81 from Final Rule, page 380.)

TABLE 81. FINAL CY 2025 STATUS INDICATORS AND APCS FOR CATEGORY I AND III CPT CODES FOR THE PREPARATION OF CAR T-CELL THERAPY

CPT Code	Long Descriptor	Finalized CY 2025 Status Indicator	Finalized CY 2025 APC
0537T	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	D	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (e.g., cryopreservation, storage)	D	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	D	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	D	5694
3X018/38225	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	B	N/A
3X019/38226	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (e.g., cryopreservation, storage)	B	N/A
3X020/38227	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	B	N/A
3X021/38228	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	5694

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 (e.g., 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 CMS to reconsider its proposed market basket increase to no less than the 3.4% it finalized in the FY2025 IPPS Final Rule.**

CMS Response: (p.149): *We acknowledge commenters' concerns, however, as we stated in the CY 2025 OPPS/ASC proposed rule, section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2025 IPPS/LTCH PPS final rule. We refer commenters to that final rule for responses regarding the issues commenters raised (89 FR 69340).*

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. 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.**

CMS Response: (p.83-84): *After consideration of the public comments we received, we are finalizing our policy as proposed, and will exclude the non-opioid treatments for pain relief identified as satisfying the required criteria for payment under section 4135 of the CAA, 2023 from the C-APC policy to ensure payment is not packaged into any C-APC and that separate payment is made in accordance with the statute. Please see section XIII.F of this final rule with comment period for a list of the products that we are finalizing would qualify for payment under the new payment policy for non-opioid drugs, biologicals, and devices for pain relief. See Table 158 on pp. 1073-1075 for detail.*

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.**

CMS Response: (p.20): [W]*e are finalizing a policy to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of $630, which is approximately two times the volume weighted average cost amount currently associated with diagnostic radiopharmaceuticals in the Nuclear Medicine APCs. We also are finalizing updating the $630 threshold in CY 2026 and subsequent years by the Producer Price Index (PPI) 1 https://www.cms.gov/medicare/coverage/evidence for Pharmaceutical Preparations. Finally, we are finalizing payment for separately payable diagnostic radiopharmaceuticals based on their Mean Unit Cost (MUC) derived from OPPS claims for CY 2025.*

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.**

CMS Response: (p.20): *For CY 2025, an add-on payment applies to radiopharmaceuticals that use Tc-99m produced without use of highly enriched uranium (HEU). For CY 2026, we are finalizing replacing the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.*

Extension of Virtual Direct Supervision of Rehabilitation and Diagnostic Services

CMS proposes 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 all efforts by CMS to extend virtual and/or remote flexibilities, since many patients have an immunocompromised state after receiving stem cell transplants and/or other cellular or gene therapies. In addition, many patients live substantial distances from the specialized centers where they receive care; having access to virtual options concurrently supports 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.**

CMS Response: (p. 877): *After consideration of the public comments we received, we are finalizing, without modification, our proposal to revise §§ 410.27(a)(1)(iv)(B)(1) and 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025.*

Caregiver Training Services

Hospitals require the availability of a dedicated caregiver for a patient who receives a stem cell transplant or other cellular or gene therapy due to the patient's extended recovery period and complex health care 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) 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, qualified and employed auxiliary team members are likely to be the ones who 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 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 that qualified and employed auxiliary team members provide to caregivers under treating clinician orders.

ASTCT asks CMS to finalize a payment policy that allows for enrolled clinicians and hospitals to bill for these services. We note 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.

CMS Response: (p.373-374): *In summary, we are proposing an interim assignment of HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) to status indictor "A" to indicate that the code is payable under a fee schedule or payment system other than the OPPS. Because we were not able to propose APC and status indicator assignments in the CY 2025 OPPS proposed rule, we will be assigning HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) comment indicator "NI" in Addendum B of this final rule. This comment indicator is for new HCPCS codes that will be effective January 1, 2025, to indicate that we are assigning them an interim status indicator and APC assignment, which is subject to public comment. We invite public comment on the interim proposed status indicators for HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3), which will then be finalized in the CY 2026 OPPS/ASC final rule with comment period. Please refer to Table 80 below for the proposed interim status indicator assignments for HCPCS codes G0541, G0542, and G0543 (placeholder codes GCTD1, GCTD2, and GCTD3) for CY 2025.*

TABLE 80: INTERIM CY 2025 SI FOR THE CAREGIVER TRAINING SERVICES HCPCS CODES EFFECTIVE JANUARY 1, 2025

HCPCS Code	Long Descriptor	Interim CY 2025 OPPS SI	Comment Indicator
G0541 (placeholder code GCTD1)	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes)	A	NI
G0542 (placeholder code GCTD2)	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)	A	NI
G0543 (placeholder code GCTD3)	Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to face with multiple sets of caregivers))	A	NI

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; we also support the 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.

CMS Response: (p.27): *We are finalizing our proposed revisions to Medicaid and CHIP regulations to codify the requirement within the CAA, 2023 for States to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. For CHIP, we are finalizing the removal of the option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums.*

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