



American Society for
Transplantation and Cellular Therapy

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

September 11, 2023

Submitted electronically at regulations.gov

Re: CMS-1786-P: CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the Calendar Year (CY) 2024 Outpatient Prospective Payment System (OPPS) Proposed Rule.

ASTCT is a professional membership association of more than 3,700 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 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 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 clinical trials examining the use of *ex vivo* genetically edited hematopoietic stem cells delivered via a stem cell transplant for treatment of genetic blood disorders, including beta thalassemia and sickle cell disease, along with immune deficiency and metabolic disorders.

The approvals—or anticipated approvals—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 2024 OPPS proposed rule, given their implications for cell and gene therapies and stem cell transplantation.



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Specifically, we request that CMS:

- Finalize mapping CAR-T revenue codes to cost centers, as proposed;
- Confirm that the proposed C-APC 5244 payment rate of \$52,758 for allogeneic transplant is correct and discuss the ratesetting methodology used;
- Update the revenue code to cost center mapping for revenue code 0815 for Stem Cells - Allogeneic;
- Eliminate packaging of separately payable drugs with status indicator “K” from C-APCs;
- Finalize the proposed APC assignment of 229 dental procedure codes and provide explicit guidance to hospitals for reporting G0330;
- Finalize proposals for OPPS payment of social determinant of health (SDOH) assessments, principal illness navigator (PIN) services, caregiver training services (CTS) and community health integration (CHI) services and provide guidance to assist in providing these services to hospital patients; and
- Address concerns of our hospital-based clinicians to ensure they can furnish and be paid for telehealth services to their patients.

The 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.

A handwritten signature in blue ink, appearing to read "M. A. P." followed by a horizontal line.

Miguel-Angel Perales, MD

ASTCT President, 2023-2024

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I. Finalize mapping CAR T-cell revenue codes to cost centers, as proposed

ASTCT appreciates that CMS considered our comments from last year’s proposed rule, recommending that the agency map revenue code series 087x and 089x to appropriate cost centers. We agree with CMS that the proposed mappings provide greater consistency with the National Uniform Billing Committee (NUBC) definitions and more accurately account for the costs of CAR-T collection, cell processing, and administration services under the OPPS. **The ASTCT urges CMS to finalize the mapping of CAR-T revenue codes to the cost centers, as proposed.**

II. Confirm that the proposed C-APC 5244 payment rate of \$52,758 for allogeneic transplant is correct and discuss the ratesetting methodology used

ASTCT is concerned that the geometric mean cost for C-APC 5244 is listed as \$71,154 in the CPT and APC cost statistics file yet, in column 4 of Table 27 published in the rule, the geometric mean cost is listed as \$52,105. CMS proposes a payment rate of \$52,758. ASTCT has evaluated the years since this C-APC was created; as shown in the chart below, the payment rate has been slightly higher than the geometric mean cost for *all* of the years except for 2023 and the proposal for 2024.

Year	HCPCS	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Median Cost	Geometric Mean Cost	CV
2019F	38240	J1	5244O	\$37,892.76	49	49	\$14,450.64	\$102,023.10	\$37,525.91	\$38,220.27	49.984
2020F	38240	J1	5244O	\$37,431.71	45	46	\$17,228.71	\$133,681.50	\$35,131.08	\$36,628.62	51.057
2021F	38240	J1	5244O	\$31,838.13	42	43	\$5,352.67	\$85,385.30	\$33,157.43	\$31,015.17	52.376
2022F	38240	J1	5244O	\$41,026.98	42	43	\$5,395.53	\$84,811.80	\$32,695.93	\$30,715.18	52.786
2023F	38240	J1	5244O	\$42,233.40	74	76	\$12,239.94	\$130,574.90	\$43,316.09	\$46,098.63	39.010
2024P	38240	J1	5244O	\$52,758.91	55	57	\$12,119.82	\$355,862.20	\$74,878.31	\$71,154.30	61.110

ASTCT requests that CMS review the data, address whether a calculation error has occurred, and provide a detailed description of how it computes the cost for this C-APC, given recent changes in the revenue code and cost reporting instructions (described in more detail below).

Additionally, we understand that CMS’ universal low-volume APC policy, adopted as of 2022, is to create a payment rate using up to four years of claims data, yet CMS does not make clear for the low-volume APCs (shown in Table 27) which years of data are being used to compute the median, the arithmetic mean, and the geometric mean amounts. We request that CMS add a column to Table 27 providing this information so that we may replicate CMS’ calculation.

Moreover, we request that CMS discuss how it determines whether to use one, two, three, or four years of data, and whether the variation in the frequency and/or the geometric mean cost from one year to the next impacts the decision taken. We are especially concerned about this for C-APC 5244, since there have been recent changes; it may be more prudent for the agency to use the most-recent two to three years of data, which better reflect donor search and cell acquisition costs, as discussed below.



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III. Update the revenue code to cost center mapping for revenue code 0815 for Stem Cells - Allogeneic

We have questions concerning CMS' revenue-code-to-cost-center crosswalk file that accompanied the CY 2024 proposed OPSS rule. In this crosswalk, revenue code 0815—which is used to report the donor search and cell acquisition charges for alloSCT—is marked as “RESERVED” for older cost report forms titled 2552-96, but reflects the NUBC’s definition of the code of “Stem Cell – Allogeneic” for current cost report form 2552-10. The NUBC added revenue code 0815 in 2017. The 2552-96 crosswalk states that charges billed under this revenue code are used for OPSS rate-setting, but does not show what cost center is used. This raises a question as to what cost-to-charge ratio (CCR) was used for these charges. For the current form 2552-10, the crosswalk lists revenue code 0815 as mapping to 112.50. Line 112 and being for “Other organ acquisition;” this would not include stem cell transplant donor search and cell acquisition costs. Certainly, this cost center would not include donor costs after 2017, at which time CMS defined new cost center 7700 for this purpose.

ASTCT is unclear how many transplant centers have ever used cost center 112.5 to report stem cell transplant donor costs. Additionally, there is no secondary or tertiary cost center listed. This raises the question of what CCR CMS uses to calculate donor costs billed under revenue code 0815 and whether that CCR actually contains donor search and cell acquisition costs.

When CMS created C-APC 5244 for allogeneic stem cell transplants in 2019, data for cost center 7700 were not yet available to use in rate-setting. In the same policy year, CMS implemented Integrated Outpatient Code Editor (I/OCE) edit 100, which requires outpatient claims with CPT code 38240 for an allogeneic stem cell transplant to report donor charges with revenue code 0815.

While there are relatively few Medicare outpatient allogeneic transplants, it is vitally important that charges under this revenue code be mapped appropriately for OPSS rate-setting. Donor costs are one of the most-significant categories of cost for allogeneic stem cell transplants. CMS will not be able to estimate appropriate donor costs if it does not utilize an appropriate CCR; as of 2017, cost center 8600 and line 112.5 should *not* include donor search and cell acquisition expenses for transplant centers following CMS instructions and, therefore, are inappropriate.

Cost center 7700 is a logical alternative for mapping revenue code 0815. However, this cost center does not include all donor search and cell acquisition costs because related donor costs of are calculated through new worksheet (WS) D-6 that was finalized in December 2022. Because WS D-6 was not available in cost reporting software until earlier this year, CMS does not have HCRIS data for these expenses and is unlikely to have the data until 2026, at the earliest.

We know that cost center 8600 and line 112.5 should no longer contain stem cell donor costs based on CMS' instructions since 2017. We also know that cost center 7700 would be



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appropriate but will not be comprehensive. Therefore, we believe that CMS should review multiple CCR options for 0815 charges, including the transplant center's overall CCR, and assess the best option to use until such time as better cost report data are available.

ASTCT was unable to estimate the impact to the C-APC of this possible change. We are also unable to determine whether CMS is mapping 0815 charges to the 8600 cost center, line 112.5 or to another cost center. Furthermore, we are concerned that a CCR of a particular department would not reflect related donor costs calculated in WS D-6. Ultimately, we do not know whether this issue could be related to the prior issue of the final C-APC 5244 payment rate being so much lower than the geometric mean cost.

ASTCT asks CMS to evaluate the impact of mapping revenue code 0815 to the hospital's overall outpatient hospital CCR until it can utilize more-accurate information for full donor costs reported in both cost center 7700 and WS D-6 in hospital cost reports.

IV. Eliminate packaging of separately payable drugs with status indicator "K" from C-APCs

ASTCT understands the role of packaging in a prospective payment system, alongside CMS' desire to incent provider efficiency through payment bundles. While we appreciate this objective, we have identified a problematic issue with CMS' packaging of status indicator "K" drugs into Comprehensive APCs. Our interest in this issue stems from the fact that providers have started treating outpatients with CAR-T cell therapy and it is possible that, when CAR-T products are administered to outpatients, some proportion of cases may trigger the medical observation C-APC (8011). This would occur when beneficiaries require observation services after an emergency department or clinic visit for product-associated toxicities on the same date and by the same hospital that administered the CAR-T product.

As of January 1, 2024, three of the six FDA-approved CAR-T products will have a status indicator "K" assigned to them. During the 2024 calendar year, two more CAR-T products will convert from status indicator "G" to status indicator "K." The current APCs for CAR-T products pay a range of \$434,918.00 - \$492,900.00, which is appropriate based on the hospital's cost to acquire the products.

The CY 2024 proposed payment for C-APC 8011 is \$2,605.72. ASTCT does not believe it is appropriate for any of these products to be reimbursed only via C-APC 8011, if triggered, plus potential outlier payment, rather than ASP+6% (along with the payment for the administration code 0540T and any other separately payable OPPS services).

In the case of CAR-T, the administration of the cellular therapy and the product itself are the primary service—meaning that they do not match the definitional intent of packaging items and services, including non-pass-through drugs in C-APCs. Rather, CMS considers them to be "ancillary, supportive or adjunctive" to the primary service. The medical observation service and associated hours of time and other codes that could trigger the C-APC all occur following the



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administration of a CAR-T cell therapy and should be considered ancillary to the CAR-T treatment itself—not the other way around.

ASTCT strongly encourages CMS to implement the HOP Panel’s recommendation to unpackage all status indicator “K” drugs from all C-APCs.

ASTCT recently conducted an analysis that showed that most C-APCs have a very small proportion of status indicator “K” drugs billed, and an even smaller proportion appear on medical observation C-APC 8011 claims—which means that this request is of a limited scope. If CMS requires additional time to study the Panel’s recommendation before proceeding with changes to its universal C-APC logic, **ASTCT requests that CMS at least unpackage all status indicator “K” drugs from the medical observation C-APC 8011; doing so will help alleviate the unintended CAR-T scenario while the agency continues to analyze the HOP Panels’ recommendation for a broader policy change applicable to all C-APCs.**

Without an exception for C-APC 8011, a hospital’s only reimbursement pathway will be outlier dollars. Given the outlier payment of 50% after the absorption of the fixed loss threshold, hospitals would sustain losses in the hundreds of thousands of dollars when CAR-T is utilized in this type of episode of care. In addition to the inadequate individual case payment, an increase in these types of cases will inappropriately impact the outlier threshold and/or distort the future rate for C-APC 8011. As more CAR-T products move from pass-through status indicator “G” to separately paid status indicator “K,” ASTCT believes that the packaging of status indicator “K” drugs will disproportionately impact CAR-T cell therapy outpatient cases.

ASTCT urges CMS to change its I/OCE logic starting in CY 2024 so that, when the medical observation C-APC assigned status indicator “J2” is triggered, all status indicator “K” drugs continue to be paid separately.

V. Finalize the proposed APC assignment of dental procedure codes and provide explicit guidance to hospitals for reporting G0330

ASTCT very much appreciates CMS’ proposals to pay for oral health care that is medically necessary according to accepted standards of practice; is reasonable, necessary, integral, and prudent to the pre- and intra- management and/or treatment of a covered medical condition; and/or for prevention of a medical complication from oral/dental pathologies. Our members agree that the evidence supports the need for dental services that are inextricably linked to chemotherapy, CAR T-cell therapy, and antiresorptive therapy. We were pleased to see that CMS’ advisors identified 229 codes as being eligible for separate OPPS payment when relevant Medicare conditions for payment and coverage are met. **We agree that the 229 identified codes should be assigned to APCs and urge CMS to finalize this proposal for CY 2024.**

We do request clarification, however from CMS on hospital reporting of HCPCS code G0330 for facility services for dental rehabilitation procedure(s) that are performed on a patient who



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requires monitored anesthesia (e.g., general, intravenous sedation [monitored anesthesia care] and use of an operating room, when one of these 229 dental codes are applicable but performed in an operating room under anesthesia). CMS has discussed adding G0330 to the list of covered Ambulatory Surgical Center (ASC) procedures and explained that G0330 should be reported in addition to one or more of the applicable dental codes when performed in an operating room under anesthesia. Given this statement, we expect the guidance to OPPS hospitals to be the same.

ASTCT asks that CMS provide explicit guidance to hospitals for reporting G0330 and one or more of the applicable dental codes when performed in an operating room under anesthesia.

VI. Address concerns of our hospital-based clinicians to ensure they can furnish and be paid for telehealth services to their patients

ASTCT understands that CMS addresses telehealth policies in the Medicare Physician Fee Schedule (MPFS) CY 2024 Proposed Rule. We ask that CMS' outpatient staff share these comments with the PFS staff, since it is important for these comments to be considered as in scope for this Proposed Rule. ASTCT appreciates the consideration and intention to implement policies that extend coverage and payment for telehealth through December 2024; this is consistent with the intent of the Consolidated Appropriation Acts of 2022 and 2023.

Our member transplant centers rely on telehealth, particularly for their immunocompromised patients. They are well-aware that the COVID-related public health emergency (PHE) flexibilities that enabled hospitals to temporarily expand outpatient locations to patient homes for purposes of the billing and payment of hospital outpatient services ended on May 11, 2023. ASTCT believes this loss in our members' ability to utilize a telehealth service will create a significant gap in coverage and payment to our member transplant centers.

Transplant and cell therapy clinicians are often located in hospital departments (i.e., the hospital is the distant site) when they furnish telehealth services to patients in homes and other originating sites. The technology, space, and ancillary staff support are provided by hospital employees and reported as hospital costs. The ability of our facility-based clinicians to furnish care via telehealth is vital to our patient population due to the distances they may have to travel to a qualified center and their compromised immunity during transplant and cell therapy treatments.

CMS proposes to pay for telehealth services furnished to patients in their homes at the non-facility physician fee schedule (PFS) rate instead of the facility-based rate until December 31, 2024. This will apply to both facility-based and non-facility-based clinicians billing telehealth services. This means that physicians will be paid a higher non-facility rate even when the clinician is located at a hospital when furnishing telehealth services to patients in their homes. Hospitals are concerned that paying physicians located in a hospital a non-facility fee for a service provided to patients in their home raises compliance risks, since much of the practice expense to support the telehealth services is furnished by the hospital where the clinician is located. ASTCT cannot stress strongly enough to CMS how important it is that facility-based



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clinicians, including our members, can bill Medicare accurately when they furnish telehealth services to patients who are in their homes. It is crucial that the distant site hospitals from which the clinicians conduct the telehealth services can be assured that they have no risk of compliance concerns.

CMS has directed clinicians to use place of service (POS) code 02 for telehealth services to patients not in their homes and POS 10 for patients in their homes as of January 1, 2024 (see CMS' telehealth fact sheet <https://www.cms.gov/files/document/mln901705-telehealth-services.pdf>). In other instructions, CMS describes the billing requirement for the clinician to use the address of where they are located in item 32 of the 1500 claim form. ASTCT believes the use of item 32 is correct for reporting telehealth services and that, when the clinician is in a hospital, the hospital address would be used on the 1500 claim. **ASTCT asks CMS to confirm the appropriate billing and payment for telehealth services when the clinician is in the hospital and the patient is in the home and that there are no concerns for the hospitals that the clinician will be paid the higher non-facility rate.**

ASTCT is also aware that, absent further Congressional action, providing telehealth to patients in their homes will no longer be covered beginning CY 2025, other than for the treatment of mental health and/or substance use disorders (SUD). ASTCT wants to support CMS and provide evidence to Congress that telehealth is needed for immunocompromised patients in their homes, just as Congress recognized beneficiaries' need when they suffer from mental health or SUD conditions. **ASTCT asks CMS to evaluate whether it has any discretion to enable telehealth for immunocompromised patients after December 31, 2024, since this is vital to the patients we serve.**

VI. Finalize proposals for OPPS payment of SDOH assessments, PIN services, CTS, and CHI services, and provide guidance to assist in providing these services to how our centers currently furnish them.

ASTCT very much appreciates that CMS understands that, for facility-based clinicians, the ancillary staff cost to furnish SDOH assessments, PIN services, CTS, and CHI services are born by the hospital—and should be able to be billed and paid under the OPPS system. In the MPFS proposed rule for 2024, CMS discussed coverage and guidelines for these services. ASTCT submitted comments about these services under that rule; we urge CMS to finalize proposals for OPPS payment of these services.

ASTCT also asks CMS to publish guidance and use cases early in 2024 that will assist providers to implement these new codes and understand what CMS expects. This is particularly necessary regarding documentation of the services from staff and orders from clinicians.

ASTCT thanks CMS for the opportunity to comment on the CY 2024 OPPS proposed rule.