ASTCT
American Society for
Transplantation and Cellular Therapy

This document contains submitted ASTCT comments and CMS responses from the CMS OPPS Final Rule, dated November 2, 2023.

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 3,000 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.

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.

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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.**

CMS Response: (p.42 – first relevant response; p. 45 – second relevant response)

Comment: *Two commenters supported our proposed revenue code-to-cost center crosswalk changes associated with CAR-T.*

Response: *We appreciate the commenters' support for our proposal.*

Additional response*: After consideration of the public comments we received, we are finalizing the proposed crosswalk, including the proposed changes associated with CAR-T.*

CAR-T Service	Revenue code	Previous Mapping	Proposed Cost Center Mapping
Cell Collection	0871	RESERVED	9000 (Clinic)
Outbound Lab Processing	0872	RESERVED	3350 (Hematology)
Inbound Lab Processing	0873	RESERVED	3350 (Hematology)
Administration- Infusion	0874	RESERVED	6400 (Intravenous Therapy)
Administration - Injection	0875	RESERVED	6400 (Intravenous Therapy)
FDA Approved Cell Product	0891	RESERVED	7300 (Drugs Charged to Patients)

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.

CMS response: Page 252

Comment: *One commenter requested clarification about the meaning of the statement "using up to four years of data" regarding the calculation of the geometric mean, arithmetic mean, and median for the universal low volume APC policy for clinical and brachytherapy APCs (88 FR 49627). The commenter also requested more information on why there was a difference in the geometric mean amount reported in the CY 2024 OPPS proposed rule in Table 27 for APC 5244 (Level 4 Blood Product Exchanges and Related Services), which was $52,105 based on claims from CY 2022 as compared to the geometric mean reported for APC 5244 in the 2 times rule discussion for the CY 2024 OPPS proposed rule, which was $71,154 and also based on claims from CY 2022 (88 FR 49628).*

Response: *When we state that we are using up to four years of data for the universal low volume APC policy for clinical and brachytherapy APCs, we mean that we will use four years of data if four years of data is available for an APC, but we may need to use between one and three years of data if fewer years of data are available. We will use the greatest number of years of data available, unless there is a substantial reason not to use a particular year of data. The data will also be for consecutive years unless, again, there is substantial reason not to use a particular year of data. For example, we stated in the CY 2024 OPPS proposed rule (88 FR 49627) that we had concerns with CY 2020 claims data as a result of the COVID-19 PHE, and*

that we were therefore using data from CYs 2018, 2019, 2021, and 2022. The commenter correctly noted that we inadvertently provided an outdated geometric mean cost for APC 5244 based on only CY 2022 claims data. Based on data available for the proposed rule, the correct geometric mean cost without low volume APC designation that should have been displayed in Table 27 for APC 5244 was $71,154.

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 OPPS 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 OPPS 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 OPPS 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 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.

CMS response: (pp. 43-45)

Comment: *A few commenters listed a number of concerns regarding the revenue code-to-cost center crosswalk mappings associated with revenue codes 0815 and 0819. They noted that the 2552-96 revenue code-to-cost center crosswalk does not show the cost center used for ratesetting. They also noted that the current 2552-10 revenue code-to-cost center crosswalk includes a primary cost center mapping to 112.50 and no secondary or tertiary cost centers listed. A commenter requested more detail around the cost reporting and billing patterns related to revenue codes 0815 and cost centers 112.50 and 7700.*

A commenter believed that the mapping for revenue code 0819 to cost center 8600 was incongruent with CMS instructions for cost reporting periods after 2017 to no longer include donor costs in cost center 8600. They believed that this mapping should not apply.

Commenters stated that cost center 7700 represented a logical alternative mapping for revenue code 0815 but noted that it did not represent all donor search and cell acquisition costs because those costs were only recently calculated through Worksheet D-6 of the Medicare cost report and that data would not be available for ratesetting for several years. They also suggested that CMS review the use of the hospital overall ancillary CCR until more accurate information could be obtained in both cost center 7700 and Worksheet D-6. A commenter also requested that CMS ensure that the Worksheet D-6 is available for all cost reporting periods beginning on or after October 1, 2020.

Response**:** *As discussed in this section and briefly in the claims accounting narrative available online, the revenue code-to-cost center crosswalk is a hierarchy that attempts to apply departmental cost center CCRs to estimate costs from charges. Where no specific CCR is available, the provider's overall ancillary CCR will be applied. There may be significant differences in the cost reports used in our ratesetting process, based on providers' charging*

structures as well as cost reporting periods. As a result, the revenue code-to-cost center crosswalk is designed to accommodate that flexibility by selecting what we believe to be the most accurate CCRs available.

The Medicare cost report form 2552-10 was implemented for cost reporting periods on or after May 1, 2010. Providers have familiarity with cost reporting using this form. While there may be a range in the cost reporting periods available, all cost report data used in ratesetting for the CY 2024 OPPS final rule with comment period are based on the Medicare cost report form 2552-10. The 2552-96 crosswalk is largely provided for historical reference purposes and not because it is actively used in our ratesetting process. However, we can consider removing those worksheets from the form if they no longer serve a purpose for hospitals.

With regard to the primary mapping of revenue code 0815 to cost center 112.50 (Stem Cell Acquisition) indicated in the display version of the revenue code-to-cost center crosswalk, the cost center was inadvertently listed as a primary mapping. The primary and sole mapping for revenue code 0815 in our current ratesetting process is to cost center 7700 (Allogeneic Stem Cell Acquisition). In cases where that cost center CCR is not available in a provider's cost report but services are billed using revenue code 0815, the overall ancillary CCR would instead be applied to reduce charges to estimated cost. We note that there are no cost reports we are including in the CY 2024 OPPS ratesetting process that report cost and charges under 112.50, and there are no revenue code-to-cost center crosswalk mappings to that cost center.

As discussed earlier, the cost reports used in OPPS ratesetting can have varying cost reporting periods and varying cost reporting structures. Therefore, the cost center CCR mappings included in the revenue code-to-cost center crosswalk are designed to accommodate this variability. For revenue code 0815 (Allogeneic Stem Cell Acquisition Services), most of the providers billing using this revenue code are also cost reporting with cost center 7700. Within our ratesetting process, the CCRs for cost center 7700 are significantly higher than those for the overall ancillary CCR; and we continue to believe that the preference should be to use the cost center 7700 CCR unless it is not otherwise available. We note that billing using revenue code 0819 (Organ Acquisition: Other donor) is extremely limited, with only a single line observed within our data. We believe that having the flexibility to use its cost center 8600 mapping where this revenue code is billed is more reflective than the overall ancillary CCR. However, we will monitor the data to determine if this cost center CCR mapping continues to remain appropriate in the future.

While we do not have any specific changes at this time associated with the data from Worksheet D-6 of the Medicare cost report form, we will review the data as they become available. Based on that review, we will consider inclusion of that data and integration into the cost estimation process, if appropriate. We appreciate commenter input as we consider possible changes in the OPPS ratesetting process we use to estimate service costs. We also note that the cost reporting software has already been updated to allow for submission of data regarding these acquisition costs for cost reporting periods on or after October 1, 2020. After consideration of the public comments we received, we are finalizing the proposed crosswalk, including the proposed changes associated with CAR-T. In addition, we are making the change to our display copy of the revenue code-to-cost center crosswalk to assign cost center 77 as the primary cost center CCR mapping for revenue code 0815.

III. 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 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.

CMS response: (p. 74)

Comment: *Several commenters requested that CMS unpackage and pay separately for all status indicator "K" drugs from C-APCs due to certain instances of high-cost drugs and biologics, such as CAR-T, being paid through C-APC 8011 and potentially impacting beneficiary access to high-cost therapies.*

Response: *We thank the commenters for their comments. We will take the issue of C-APCs and payments for high-cost drugs into consideration for future rulemaking.*

Note: *The HOP Panel agreed with ASTCT's presentation request made before the Panel in August (see 02:55:23 of the recorded meeting file). CMS typically states and responds to all HOP Panel's recommendations in the final rule. The ASTCT has reached out to CMS about this omission and has requested the information be included in a correction notice.*

IV. 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

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.

CMS Response: (pp. 839-842 for following section; dental section continues to 869)

Comment: *We received several comments expressing concern over the impact of the proposed payment rate for HCPCS code G0330 for CY 2024. One commenter requested that we recalculate the payment rate for the APC. Another commenter stated that because the proposed G0330 payment rate for HCPCS code G0330 is 45 percent lower than the CY 2023 payment rate, and even lower for the ASC payment, the payment rate may be insufficient in light of specialized dental equipment and personnel required to furnish these services in hospital outpatient departments and ASCs. Another commenter stated that the inadequacy of the proposed payment rates for HCPCS code G0330 for both hospital and ASC settings is likely to stymie use of the code. Several commenters urged CMS to not finalize our proposal to continue to assign HCPCS code G0330 to APC 5871 due to concerns over the APC's payment rate. Some commenters requested that CMS finalize an APC reassignment for HCPCS code G0330 from APC 5871 to APC 5164 (Level 4 ENT Procedures) with a proposed payment rate of $3,087.88 for CY 2024. One commenter stated that reassignment to APC 5164 would be consistent with available cost and charge data for dental procedures likely to be reported using HCPCS code G0330. To support their request for reassignment to APC 5164, commenters stated that prior to CMS's establishment of HCPCS code G0330, these same dental rehabilitation procedures were reported using unlisted CPT code 41899, with a geometric mean cost of approximately $2,200, which is within the range of costs for procedures classified into APC 5164. Another commenter stated that CMS's proposal to allow for multiple procedure discounting for HCPCS code G0330 by proposing to assign status indicator "T" to the code would further lower the payment rate for services described by the code.*

We are clarifying that providers should bill any other more specific CPT and/or CDT codes assigned to APCs that describe the service performed, instead of HCPCS code G0330, whenever possible. HCPCS code G0330 should only be billed when no other, more specific code is available to describe the service performed. (p.838)

Response: *We thank the commenters for their input. First, we note that APC geometric mean costs can change from year to year as a result of data updates and policy changes. In this case, we proposed to assign 229 dental procedures to APCs, with many proposed for assignment to APC 5871, the same APC to which HCPCS code G0330 was proposed to be assigned.*

Additionally, we proposed to change the APC assignments of some codes that were previously paid under the OPPS based on clinical similarity, including codes describing dental imaging services. We also note, APC 5871 is an APC with a low volume of claims and, therefore, is more prone to volatility in its geometric mean cost and payment rate changes from year to year based on the claims data available for ratesetting. The proposed coding changes, as well as the fact that APC 5871 has a low volume of claims, resulted in an unintentional reduction to APC 5871's geometric mean cost and payment rate for CY 2024. As we explained in our proposal for CY 2024, we encountered various challenges in securing accurate cost information for the hospital outpatient setting for the dental codes we proposed to assign to APC payment rates. We believe that as utilization increases and we receive claims data on the codes that we proposed to assign to various APCs for CY 2024, we will make changes to APC assignments and APC groups, including considering creating additional APC levels and new clinical APCs in future rulemaking, based on clinical and resource needs.

We reiterate that the proposed payment rate for the services assigned to the Dental Procedures APC was the result of our ratesetting process, which we apply consistently to set the payment rates for other clinical APCs. With that said, we are sympathetic to commenters' concerns regarding the reduction in the proposed payment rate for HCPCS code G0330 from CY 2023 to CY 2024, especially without having claims data for the code that would indicate that the proposed payment rate is appropriate. Based on comments received stating that CPT code 41899 was used to describe the services currently described by HCPCS code G0330 prior to the code's effective date of January 1, 2023, we analyzed the available claims data for surgical claims for CPT code 41899 in CY 2021 to get a benchmark for the geometric mean costs of services that are described by HCPCS code G0330. While CPT code 41899 is an unlisted code describing unlisted procedures on the dentoalveolar structures that may or may not be surgical in nature and performed under the same conditions as described by HCPCS code G0330, we ran a study to isolate the claims performed with monitored anesthesia codes to more closely mimic the conditions required for services billed under HCPCS code G0330. Based on this analysis, we believe that the proposed APC assignment for HCPCS code G0330 for CY 2024 would be inappropriate in terms of estimated resource costs. Therefore, for CY 2024, we are not finalizing the APC assignment of HCPCS code G0330 to APC 5871 as proposed.

Although we believe isolating the surgical claims gives us a better idea of the geometric mean costs of HCPCS code G0330, we also believe that the approximation using surgical services billed with CPT code 41899 will not be as accurate as the claims information we will receive for HCPCS code G0330 in future years. We also note the crosswalk to CPT code 41899 is not a perfect comparator given that it is an unlisted code, which, per our billing instructions, should only be used when there is no other more specific code available. Therefore, we will determine whether the APC assignment we are finalizing for HCPCS code G0330 is appropriate based on claims data received in future years and consider further APC assignment changes in future rulemaking. However, based on the comments received, the fact that we do not have existing claims data for HCPCS code G0330 at this time, and our analysis of surgical claims using CPT code 41899, which demonstrate that the geometric mean costs for surgical claims for CPT code 41899 are notably higher than the proposed payment rate for procedures assigned to APC 5871 for CY 2024, we believe reassigning HCPCS code G0330 from APC 5871 to APC 5164 is appropriate for CY 2024.

After consideration of the public comments we received, we are finalizing an APC reassignment for HCPCS code G0330 from APC 5871 to APC 5164 with status indicator "J1" for CY 2024. We refer readers to Addendum B to this final rule with comment period rule for the final CY 2024 APC assignment and associated payment rate for HCPCS code G0330. Addendum B is available via the Internet on the CMS website. We also refer readers to Addendum D1 for a definition of status indicators including "J1."

V. 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 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.**

CMS response: (p. 830)

Comment: *One commenter emphasized the importance of CMS providing explicit billing guidance when clinicians in hospitals furnish telehealth services to patients in their homes. The commenter requested that CMS confirm the appropriate billing and payment for telehealth services when the clinician is in the hospital and the patient is in the home and asked several specific billing questions.*

Response: *We direct the commenter to the CY 2024 PFS final rule for specific information relating to billing for telehealth services furnished to patients in their homes. We will consider additional sub-regulatory clarifications, as needed, in the future.*

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.**

CMS response: *There was no response from CMS in the Final Rule.*

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.

CMS Response: *There was no response from CMS regarding these services other than in the context of behavioral health partial hospitalization programs (PHP) and intensive partial hospitalization programs (IOP). The ASTCT is seeking clarity from CMS on this issue; in the interim, please refer to MPFS rule and CMS' comments there regarding these services in facilities and by facility-based clinicians.*