ASTCT
American Society for
Transplantation and Cellular Therapy

June 17, 2022

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

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the LongTerm Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and NonQualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation [CMS-1771-P]*

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit comments on the FY 2023 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule.

The 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. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current 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. One of the biggest innovations in recent years has been the launch of CAR-T therapies. CAR-T and other engineered cellular therapies (cell therapies) are unlike any other types of therapeutics available today and are also distinct from prior types of cellular therapy, such as hematopoietic stem cell transplantation (HSCT). ASTCT members are involved in the infusion of cell therapies for conditions other than blood cancers, like tumor-infiltrating lymphocytes (TILs) 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.

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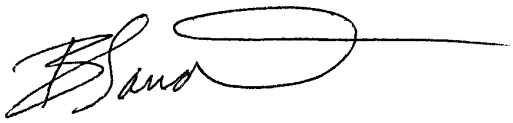
The approvals—or anticipated approvals—of novel cellular immunotherapies and gene therapies have highlighted challenges within the Medicare coverage, coding, and payment systems. The ASTCT remains concerned about the potential barriers to care these challenges may cause. We are committed to working with CMS to find solutions that ensure patient access to these therapies without creating financial harm to the clinicians providing them. And if CMS has any questions, please contact Alycia Maloney, the ASTCT's Director of Government Relations, at amaloney@astct.org.



Brenda Sandmaier, M.D.
ASTCT President, 2022-2023

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Executive Summary

ASTCT appreciates the opportunity to provide comments to CMS regarding the FY 2023 IPPS Proposed Rule. We address the following points in more detail throughout the remainder of the letter.

1) **MS-DRG 018 - Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies:**
   - The ASTCT appreciates and supports CMS' proposal to continue the unique payment and rate-setting methodologies currently in place for MS-DRG 018.
   - The ASTCT is encouraged by CMS' ongoing consideration of additional engagement mechanisms with stakeholders in the cell and gene therapy space and encourages CMS to utilize public discussion forums, such as Town Halls and listening sessions.
   - The ASTCT requests that CMS identify a mechanism for public discussion of those procedure codes originating from the annual March ICD-10-PCS meetings that are proposed for mapping to MS-DRG 018 each October 1, and that CMS provide a working definition for "other immunotherapies" that stakeholders can reference.
   - The ASTCT disagrees with the 087x series being mapped to the drug cost group and also requests that CMS provide a detailed order of operations for how it calculates the relative weight for MS-DRG 018.
   - The ASTCT requests that CMS consider some of the technical suggestions provided by the ASTCT (Appendix A) to continue improving rate-setting for the IPPS system, and specifically MS-DRG 018.
2) **MS-DRG 014 – Allogeneic Bone Marrow (Stem Cell) Transplantation**
   - The ASTCT urgently requests that CMS release updated cost reporting instructions associated with Section 108, which provides for reimbursement of donor cell and acquisition costs on a reasonable cost basis.
   - The ASTCT suggests that CMS modify the cost group mapping for the administration of stem cells and also update the accompanying manual instructions.
3) **Requests for Information:**
   - The ASTCT requests that CMS begin a study of potentially utilizing Medicare Advantage shadow claims for purposes of increasing the volume of claims available for rare diseases, conditions and procedures, as well as potentially incorporating the data into rate-setting.
   - The ASTCT supports CMS' goal of incorporating the social determinants of health and will share with CMS the findings from an upcoming society meeting devoted to this topic.
4) **General IPPS Commentary:**
   - The ASTCT supports CMS' proposed methodology for calculating FY 2023 relative weights, but is concerned with the significant increase in the outlier fixed loss threshold.
   - The ASTCT suggests that CMS should delay implementation of utilizing National Drug Codes for NTAP payment purposes until a technical advisory group can provide insight on multiple operational issues of concern.
   - The ASTCT requests that CMS publish an example calculation of when two or more NTAP therapies are utilized within a single inpatient stay.
   - The ASTCT requests that CMS consider the financial incentives that the significant cost determination process has on Medicare Advantage plans requesting National Coverage Analyses for new and high-cost therapies, as well as the burden this linkage will create for stakeholders as more cell and gene therapies are approved.

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MS-DRG 018 - Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies

The ASTCT greatly appreciates the exceptional changes CMS has made to its payment and rate-setting methodologies for MS-DRG 018 (Chimeric Antigen Receptor T-cell and Other Immunotherapies) in recognition of the unique circumstances associated with CAR-T and similar therapies. The ASTCT continues to invest significant time and resources to member education associated with CMS' coverage and reimbursement provisions, including the development of a *CAR-T Coding & Billing Guide* meant to highlight and consolidate CMS' instructions for hospitals.[1]

This work with our members also provides an opportunity for dialogue with hospital revenue integrity and finance staff, which helps to identify remaining areas of confusion or concern. We have included several of these technical issues in an appendix at the end of the letter with a focus on the ways that the agency could improve the overall quality and consistency of provider claims data to use in future rate-setting while continuing to reduce provider administration burden. As the volume of CAR-T administration grows in the Medicare beneficiary population, we anticipate the identified issues to be of increasing concern to PPS hospitals and CMS alike.

Support for Continuation of MS-DRG 018 Payment and Rate-Setting Methodology

Given their specialty, ASTCT physician members are responsible for providing the clinical care associated with CAR-T therapy and other immunotherapies, which map to MS-DRG 018. Thus, the ASTCT appreciates and supports CMS' proposal to continue the unique payment and rate-setting methodologies currently in place for MS-DRG 018. Appropriate reimbursement is imperative to our members' ability to continue providing access to CAR-T therapies.

In the proposed rule, CMS noted unique issues with the latest MedPAR data around CAR-T therapies. We agree with CMS' comments that "*the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy.*"[2] We believe there are many reasons for the variance, including concerns about public perception, and misunderstandings about the rules on appropriate charging practices, despite CMS' comments on this topic in the FY 2022 and FY 2021 final rules. Furthermore, we continue to see a high overall proportion of clinical trial cases, as identified by the Z00.6 diagnosis code on CAR-T therapy claims.

In recognition of these issues' significant impact on the data for cases that group to MS-DRG 018, we agree with CMS' proposal to continue to apply a modified payment and rate-setting methodology to this MS-DRG. The persistence of these issues indicates that the methodology CMS uses for rate-setting for CAR-T remains relevant and necessary.

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[1] ASTCT, *CAR-T Coding & Billing Guide*, available at: https://www.astct.org/advocate/car-t-coding-and-billing-guide
[2] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28252.

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Analysis of MS-DRG 018 Cases

We also appreciate CMS' efforts to provide transparency about the cases that make up MS-DRG 018, as displayed in the table shown in the proposed rule.[3]

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs	Secondary Diagnosis Z00.6
018	All cases	558	16.5	$194,717	185
	XW033C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	50	13.2	$212,265	16
	XW033M7 - Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	11	14.1	$157,950	4
	XW033N7 - Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	4	11.3	$310,561	1
	XW043C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	435	16.7	$186,038	152
	XW043M7 - Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	43	20.3	$264,932	7
	XW043N7 -Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	15	14.2	$182,700	5

We note that the timeframe for the data being analyzed (FY 2021 reflecting discharges from October 1, 2020 - September 30, 2021) does not match the timeframe during which the codes shown in the table were available. The New Technology Group 7 codes utilized in the table were effective as of October 1, 2021, for the start of FY 2022—one year later than the data shown in the table. We received several questions about the codes in this table and assume that CMS mapped cases coded with 2021 PCS codes to 2022 PCS codes.

The ASTCT requests that CMS continue to provide information on volumes of cases within MS-DRG 018, as it is very helpful to stakeholders. We also request that CMS either utilize the codes available during the claims data period being analyzed or provide clarification about any mapping of cases across time periods that is being done as new codes are released. This will help avoid confusion for readers and stakeholders interested in the usage of specific products.

Engagement of Stakeholders: Cell and Gene Therapies

In the proposed rule, CMS summarized the feedback and suggestions that the agency received in response to its remark (in the FY 2022 IPPS final rule) that it would continue to engage with stakeholders on the issue of cell and gene therapies and the IPPS. CMS mentioned receiving recommendations for town hall meetings/listening sessions, and the evaluation of the creation and assignment of multiple MS-DRGs for cell and gene therapy cases: one to cover patient care costs,

[3] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28131.

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and the other to therapy/product-related costs across therapeutic categories.[4] This indicated to us that the agency is continuing to consider stakeholder suggestions for engagement in relation to cellular and gene therapies, and we want to expound on a few of these suggestions.

CMS previously held a series of Town Hall sessions entitled "transitional coverage for emerging technologies."[5] While these sessions were almost entirely focused on devices, we applaud CMS for the concept and for soliciting stakeholder input on ways to make innovative technologies more accessible to its beneficiaries. We wish to see similar Town Hall sessions focused on addressing the issue of appropriate rate-setting and reimbursement within the IPPS system for novel cell and gene therapies.

Assignment of Procedure Codes to MS-DRG 018

CMS stated in the proposed rule that it had received comments about MS-DRG 018, asking CMS to assess whether or not to map newly approved ICD-10-PCS codes to MS-DRG 018 within rulemaking. Currently, ICD-10-PCS codes that are discussed at the spring ICD-10 Coordination & Maintenance (C&M) Committee meeting do not receive proposed assignments and are not published with the IPPS proposed rule, given the timing. Rather, CMS assigns them to MS-DRGs and they become effective at the start of the immediately following fiscal year (October 1). This means that there is no opportunity for stakeholders to provide feedback to CMS about MS-DRG assignments for new codes for MS-DRGs, including MS-DRG-018. We understand the concern raised by these commenters and the ASTCT supports close monitoring of therapies that will be assigned to MS-DRG 018.

The ASTCT asks CMS to consider establishing a period for proposal and comment for procedure codes potentially assigned to MS-DRG 018 after their approval(s) at the annual spring ICD-10 C&M meetings.

CMS notes that the time frame of the spring meeting prohibits inclusion of the codes within the IPPS proposed rule. For this reason, the agency utilizes established processes to propose MS-DRG assignment, including review of the predecessor codes, consideration of severity of illness, complexity of service and resources utilized in the diagnosis or treatment of the condition, and input from its clinical advisors. Stakeholders have valuable feedback that can aid the agency's decisions about these assignments. Given that MS-DRG 018 is a Pre-MDC MS-DRG with a limited current number of procedures mapped to it, we believe it is important to allow stakeholders to preview therapies' potential assignment to MS-DRG 018 prior to finalizing the decision, in order to provide feedback to CMS. This is important as the current therapies assigned to this DRG are almost singularly unique in their clinical profile, their clinical resource-intensity, and the costs to hospitals in acquiring these products.

[4] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28131.
[5] Centers for Medicare and Medicaid Services. "Transitional Coverage for Emerging Technologies Listening Session" Transcript; March 31, 2022.

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The ASTCT has a unique relationship with the therapies currently mapped to MS-DRG 018. Our membership is currently the predominant specialty associated with the procedures mapped to MS-DRG 018, and thus has deep understanding about the clinical resource patterns and utilization of the cellular products being administered during these episodes of care. Our members' experience would likely be useful to CMS when it assesses which procedure codes are most appropriate to assign to MS-DRG 018. We understand and appreciate that CMS has well-established advisors and processes for making these decisions; however, we wish to offer our clinical expertise as an additional resource given the novel nature of these therapies and our membership's role in providing these services to Medicare beneficiaries.

We also believe that CMS would benefit from multiple avenues for accepting feedback, in addition to written comments. We understand that the ICD-10-PCS meeting is not an appropriate place for the public to provide MS-DRG assignment input. For this reason, we request that CMS create an appropriate forum or mechanism for the public to provide input early in the MS-DRG 018 assignment process for new therapies.

The ASTCT also requests that CMS establish a definition for "Other immunotherapies" that may be assigned to MS-DRG 018. In the proposed rule, CMS stated that "*there were no requests for new procedure codes to describe the administration of a CAR T-cell or another type of gene or cellular therapy discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee meeting*."[6] CMS' use of "*gene or cellular therapy*" in the context of codes that may be considered for inclusion in MS-DRG 018 gives us pause: non-cellular gene therapies (currently those considered to be *in vivo* gene therapies) would not align with the ASTCT's working definition of "other immunotherapies."

We ask that CMS clarify whether the statement in the proposed rule was meant to imply that non-cellular gene therapies would be considered for mapping into MS-DRG 018. We request CMS to help stakeholders better understand the types of therapies the agency considers to be "other immunotherapies." Our understanding is that CMS intends for MS-DRG 018 to encompass novel cellular immunotherapies delivered via a single episode of care, and the ASTCT supports this premise. We do not believe that every cell and gene therapy would be appropriate to assign to MS-DRG 018, as not all of them would align with the resource and clinical homogeneity frameworks utilized by CMS when considering DRG assignment.

Request for Modifications to FY 2023 CAR-T Service Revenue Code Mapping

The documents associated with the proposed rule include CMS' annual revenue code-to-cost-center mapping file. This file contains a detailed listing of all National Uniform Billing Committee (NUBC) revenue codes assigned to individual cost centers in the cost report and is designed to match patient care revenue and hospital expense.

The FY 2023 file includes CMS' first assignment of revenue codes in the 087x series to cost center

[6] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28130.

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lines and the IPPS cost group. The 087x revenue codes are used to report CAR-T therapy services and may be reported on MS-DRG 018 inpatient claims. We are concerned that CMS' the FY 2023 file maps revenue codes 087x for cell and gene therapy clinical services furnished by hospital staff into the drug cost group. The NUBC 2022 UB-04 manual definition states this revenue code series is for *"[c]harges for procedures performed by staff for the acquisition and infusion/injection of genetically modified cells"* (emphasis added).

The ASTCT's MS-DRG classification letter, submitted November 1, 2021, requested that CMS use an appropriate mapping of the 087x revenue code series to cost groups that more closely reflects the departments where hospitals record the expense of staff performing the services. We appreciate CMS' clarification of the mapping of these codes, but **ASTCT disagrees with the 087x series being mapped to the drug cost group.** The cost report does not have a standard cost center for hospital-employed nursing and laboratory staffs' expenses associated with the 087x series. Nonetheless, the ASTCT believes it is *inappropriate* to assign the revenue for cell collection and processing services performed by staff to the drug/pharmacy cost center.

The staff performing these services are not pharmacists and, therefore, their expenses do not roll up to pharmacy cost centers in hospitals' general ledgers in the same manner as drugs and biologicals billed with revenue codes 025x, 063x, and 089x. Per the NUBC, the new cell and gene product revenue code series 089x is an extension of pharmacy and does belong in this cost group. The cost center lines for the expense in the drug cost group are for drugs and biological products charged to patients plus pharmacy direct, overhead, and handling expense.

If CMS finalizes its proposed mapping for revenue code 087x, it will ignore the proper matching of patient care revenues and expenses that hospitals are required to adhere to in their cost reports. This is no different than if CMS were to take clinical laboratory revenue billed with revenue code 030x and map it to the Operating Room cost group. Doing so would reflect a misalignment of hospital revenues and expense.

CMS' use of 19 cost groupings for IPPS rate-setting is intended to reflect a roll-up, or aggregation, of hospitals' matched expense and revenue for like services. The accuracy of this mapping is crucial, because CMS uses the resulting cost-to-charge ratios (CCRs) to estimate costs that are used to develop MS-DRG relative weights. CMS' guidance is that "*providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report*." [7]

The ASTCT proposes an alternative, more accurate mapping in the following chart. This proposed process will foster alignment based on where CMS mapped other revenue codes that are representative of similar and/or the same staff expense. Our November 1st letter suggested the cost report lines for each of the CAR-T service revenue codes; the table below provides our recommendation for cost group assignment in keeping with the Excel file format. The table illustrates examples of other revenue codes that map to the cost group we recommend and that match our prior recommendations. Following the table, we provide our rational for the

[7] CMS, *Medicare Claims Processing Manual*, Chapter 4 section 20.5.

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recommended cost groups.

Revenue Code	NUBC Description	Recommended Cost Group	Other revenue codes with similar expense mapped to the recommended cost group
0871	Cell Collection	Other	0510, 0761, 0940, 0949
0872	Specialized Biologic Processing and Storage - Prior to Transport	Laboratory	030x, 031x
0873	Storage and Processing after Receipt of Cells from Manufacturer	Laboratory	030x, 031x
0874/0875	Infusion/Injection of Modified Cells	Other	0510, 0761, 0940, 0949

- *0871 for Cell Collection:* Staff who perform apheresis collections are licensed nurses associated with clinics and/or other therapeutic departments of hospitals that furnish apheresis services. The services are billed with revenue codes 051x, 076x, and 0940. Given that this service is usually performed by nursing staff in these departments, we believe the most appropriate cost group for 0871 is the "other" cost group.

- *0872 and 0873 for Cell Processing:* Staff who perform cell processing services reported with revenue codes 0872 and 0873 are the same staff who perform laboratory services reported with revenue codes 030x and 031x. These services map to the laboratory cost group; therefore, it stands to reason that the most appropriate cost group mapping for 0872 and 0873 should be the "laboratory" group.

- *0874 and 0875 for Infusion and Injection of Modified Cells:* Staff who perform infusion and injection of cell therapies are licensed nursing staff who are trained for this purpose. These staff are associated with therapeutic departments of the hospitals that furnish stem cell transplant services. They best match the cost group mapping of 051x, 076x, and 0940.

Calculating the Relative Weight of MS-DRG 018

The ASTCT is deeply invested in a close analysis of the data associated with MS-DRG 018. But because CMS uses a unique method for MS-DRG 018 rate-setting and does not explicitly describe the order of operations, it is difficult for our analysts to replicate the rule, match CMS' proposed relative weight, and begin new simulations. In trying to resolve the discrepancies we see, our analysts invest significant time and resources guessing at the steps CMS took and the order in which those steps were applied.

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To improve this situation, we ask CMS to provide additional clarification on the agency's methodology to develop the relative weight. If CMS were to publish details about the order of operations for both MS-DRG 018 and its overall rate-setting methodology, stakeholders would be able to replicate the rule in a quick and accurate manner. This would facilitate stakeholders' running simulations, identifying concerns and potential alternatives, and exploring new models requested by CMS for low-volume MS-DRGs and rare diseases. This clarification would enable the ASTCT and other stakeholders to accurately replicate the proposed relative weight using MedPAR data and the AOR/BOR files that CMS releases with the rule.

As a result of our difficulties in replicating CMS' rule, and specifically the relative weight for MS-DRG 018, the ASTCT requests the following of CMS:

1. Release detailed information describing the order of operations used to develop relative weights, including detailed step-by-step instructions of when to exclude certain types of claims along the data analytic continuum. This information could appropriately be provided either in the final rule, future proposed rules, and/or in a separate document. Our request mirrors what CMS began to release many years ago for OPPS: a robust Claims Accounting document that accompanies each OPPS rule and truly facilitates data analysts' ability to quickly complete replication.

2. Clarify in the final rule how CMS arrived at the claims data used to develop the relative weight for MS-DRG 018. Specifically, we ask CMS to clarify whether the agency trims claims first, or sets aside clinical trial cases as well as those with charges less than $373,000 and then performs trimming.

Request for a Study of the Standardization Methodology Applied to MS-DRG 018

The ASTCT has invested significant time and resources in educating our membership about the importance of setting appropriate charges that are reasonably related to cost, as required by CMS in the *Provider Reimbursement Manual* (Part 1 Section 2202.4). We often remind our stakeholders that CMS reiterated this requirement in both the FY 2021 and FY 2022 IPPS final rules.[8] We also monitor MedPAR claims data for trends that can inform provider education and outreach work, and to try to anticipate potential issues with rate-setting that may impact access to novel cell therapies.

Our preliminary analysis of recent claims data for cases that map to MS-DRG 018 is that some providers appear to heed CMS' guidance about setting their charges in accordance with their CCRs. We have also noticed that, unfortunately, the standardized cost of these charges (rather than simply the charges reduced to cost by the providers' CCR) appears to be lower than the products' known acquisition costs.

One reason for this may be due to the impact of the wage index on standardizing charges, since CMS uses the same labor share for all 19 cost centers. When the wage index is greater than 1.0, the

[8] Centers for Medicare and Medicaid Services (CMS), "FY 2022 Inpatient Prospective Payment System (IPPS) Final Rule," *Federal Register,* 2021; 86(154): 44965.

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labor share is 67.6 percent; when the wage index is 1.0 or less, the labor share is 62 percent. CMS uses these overall "average" labor share portions in its standardization and adjusts each of the 19 cost centers by these same proportions.

We encourage CMS to study whether this uniform application is appropriate for MS-DRG 018 and/or other MS-DRGs, since labor share varies dramatically by cost center group. For example, the labor share is very high for routine and intensive nursing cost centers and much lower for the cost centers for supplies, implants, and drugs or pharmacy costs.

The ASTCT asks that CMS study whether changes to standardization might be appropriate—such as defining the labor portion individually for each of the 19 cost centers and only standardizing that portion, especially if doing so improves the overall explanatory power of all MS-DRGs. We request that CMS study this and release its analysis on this in future rulemaking. We recognize that any change impacting standardization would require careful time and analysis, and be conducted in collaboration with other IPPS stakeholders. Thus, we raise these questions now for CMS to consider and discuss among stakeholders given the trend is likely to become problematic as more therapies are approved.

MS-DRG 014 - Allogeneic Bone Marrow (Stem Cell) Transplantation

Section 108: Hematopoietic Stem Cell Acquisition Costs

Section 108 of the Further Consolidated Appropriations Act (i.e. Section 108) of 2020 (Pub. L 116-94) mandated that costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant are not included in the definition of "operating costs of inpatient hospital services," and that hospitals will be reimbursed on a reasonable cost basis for cost report periods beginning on or after October 1, 2020. The hospitals with a cost report period beginning on October 1, 2020, finished their first full fiscal year under this new payment on

September 30, 2021. Upon completion of their fiscal year, those hospitals began their usual five-month process of preparing their cost reports for submission, which were due on February 28, 2022. This first wave of hospitals is now nearing the completion of their *second* full fiscal year under the new payment mechanism. Yet, they have not received the detailed cost report instructions necessary to accurately submit costs and receive reasonable cost reimbursement. CMS issued draft cost reporting instructions in early 2021 and the ASTCT submitted comments in response to these draft instructions. The ASTCT initially anticipated having revised cost reporting instructions for review and comment in Q2 or Q3 of 2021 and is disappointed that this did not occur. We remain concerned about the lack of instructions, which are critical to hospitals filing in a timely manner and submitting complete and accurate cost reports. Moreover, hospitals that have already completed their annual cost reports will have to amend and refile when the instructions are eventually received.

The ASTCT urges CMS to specify, in the final rule, *when* revised cost reporting instructions will be released, where specifically on its website they will be located, and how much time providers will have to submit comments. We also request that CMS require MACs to allow for a minimum of

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120 days for hospitals to implement the instructions and amend their cost reports accordingly. We anticipate that there will be significant associated rework on the part of the hospitals to amend their cost reports to comply with CMS instructions.

We also reiterate our request that CMS require Medicare Advantage (MA) plans to provide information to CMS and in-network facilities on how they have adjusted their payment rates to contracted hospitals, since costs for donor cell acquisition are no longer reflected in the MS-DRG 014 payment rate that MA plans typically use as a payment benchmark. The ASTCT also requests that CMS verify that for non-contracted hospitals, MA plans are expected to mirror Fee-For-Service (FFS) payment parameters and that part of their payment methodology should include providing reasonable cost reimbursement for donor stem cell acquisition costs. We request that CMS update its MA Payment Guide for Out-of-Network Payments accordingly.

FY 2023 Revenue code mapping: Stem cell transplant

In addition to reviewing the revenue-code-to-cost-center mapping for CAR-T services, the ASTCT also reviewed the mapping for stem cell transplant (SCT). As a result of our review, we request that CMS revise the cost group mapping for the administration of hematopoietic stem cells.

Hospitals are likely to currently utilize revenue code 0362 for administration of hematopoietic stem cells due to CMS' instructions to report allogenic stem cell services with 0362 defined as "other organ transplant." (These instructions were provided in in the Medicare Claims Processing Manual, Chapter 3, section 90.3.1 and Chapter 4, section 231.11) Revenue code 0362 maps to the Operating Room (OR) cost group. Yet, SCTs are not performed in ORs and, thus, this mapping does not match the department that incurs having the expense of SCTs.

In the ASTCT's comment letter on the FY 2018 IPPS Proposed Rule, we discussed the appropriateness of CMS' proposal to reclassify multiple autologous and allogeneic stem cell transplant ICD-10-PCS codes from OR to non-OR status. We acknowledged that transplant cases are not OR procedures and CMS made the change to treating these procedures as pre-MDC, non-OR procedures. Therefore, it is illogical for CMS to continue to instruct hospitals to utilize an OR revenue code (0362) that maps to the OR cost group for IPPS rate setting.
Furthermore, SCTs do not meet the NUBC definition of revenue code 0362 for "other organ transplant," since *stem cells are not organs*.

The ASTCT requests that CMS update Section 231.1.1 in the manual and instruct providers to utilize a different, more appropriate revenue code that reflects where costs are actually incurred. For example, 0940 ("other therapeutic service") might be a better revenue code for SCT procedures, since the administration of stem cells by infusion or injection (i.e., a stem cell transplant) is a therapeutic service often performed at the patient's bedside or in a treatment room. Therefore, the cost group mapping for revenue codes 0940 is the "other" cost group. We ask that CMS update the cost group mappings for the FY 2023 IPPS final rule and also update the manual instructions.

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Requests for Information

Rare Diseases

The ASTCT is very pleased that CMS is *"soliciting comments to explore possible mechanisms through which [it] can address rare diseases and conditions that are represented by low volumes in…claims data."*[9] The majority of patients that ASTCT members treat are individuals with rare hematologic malignancies and hemoglobinopathies. As a result, the number of cases within the relevant MS-DRGs that reflect beneficiary treatment is very limited, as displayed below.

MS-DRG	MS-DRG Title	Volume (FY 2023 BOR file, inclusive of Covid)
014	Allogeneic bone marrow transplantation	1117
016	Autologous bone marrow transplantation with CC/MCC	2029
017	Autologous bone marrow transplantation without CC/MCC	17
018	CAR-T and other immunotherapies	386

As the agency indicates throughout each rule, CMS utilizes only those claims paid by FFS Medicare for services rendered at PPS hospitals for purposes of rate-setting and the evaluation of potential creation of MS-DRGs or splits of existing MS-DRGs. CMS also states:

> *As previously noted, we generally seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets. We have been concerned that basing MS-DRG reclassification decisions on small numbers of cases could lead to complexities in establishing the relative payment weights for the MS-DRGs because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability and thus predictability for hospitals for annual updates to the relative payment weights. As also previously noted, the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. However, as noted, cases involving treatment of rare diseases may involve more resource use than other cases in their respective MS-DRG.* [10]

The ASTCT recommends that CMS study how the use of Medicare Advantage shadow claims could be used to bolster case volumes for the treatment of rare diseases and conditions.

In 2021, more than 40 percent of Medicare beneficiaries were enrolled in MA plans; this is a dramatically different landscape than only 10 years ago, when the MA enrollment rate was just

[9] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28195.
[10] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28196-7.

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above 10 percent.[11] The Congressional Budget Office (CBO) projects that this trend will continue, with the share of all beneficiaries enrolled in MA plans rising to approximately 51 percent by 2030.[12]

MA enrollment also varies significantly across the United States, with substantially higher enrollment in MA on both coasts, the populous Southern states (e.g., Texas, Tennessee, Georgia and Florida) and the upper Midwest.[5] This variation means that the FFS claims that Medicare utilizes are not only decreasing in total number (now representing only 50-60 percent of enrollees) but also are becoming increasingly less representative of the national population's geographic distribution.

Finally, the states where MA enrollment is the highest are also those states with the highest number of academic and specialized medical centers, where many patients with rare diseases seek specialized care. These factors create a situation where claims from a limited number of centers in certain geographic areas of the country will drive an increasing share of the rate-setting data, even though they may not be representative of the majority of the patients and/or care being provided.

In addition to the decreased FFS claims volume creating rate-setting concerns within the FFS segment itself, we note that MA plans frequently utilize FFS MS-DRG base payments for their payment benchmarks. For the reasons stated above, the use of a set of claims that is no longer nationally representative to establish payment to hospitals treating MA beneficiaries is neither logical nor appropriate.

Given the current and further predicted diminished volume of FFS claims, we encourage CMS to consider the use of MA shadow claims for 1) establishing new and/or splitting current MS-DRGs, and 2) rate-setting for rare diseases and procedures, such as the administration of CAR-T.

Including MA shadow claims in CMS' analysis of total case volume may assist in identifying enough cases associated with the treatment of rare diseases to consider the establishment of a new MS-DRG or the splitting of a established MS-DRG, based on CMS' current parameters.

In terms of rate-setting, CMS could model the inclusion of MA claims on relative weights and share the findings with stakeholders for feedback. A higher volume of claims should make the analyses CMS conducts on claims more statistically robust, giving CMS the greater stability it seeks for MS-DRG payment rates, while also ensuring that MA payment benchmarks are more representative of the patients and care provided.

We recommend that CMS commission a study with a trusted partner to examine the potential to include shadow claims in either or both of these processes. CMS could identify several low-volume services, diseases, or MS-DRGs to model in the study, such as MS-DRG 018, in order to understand if and how the volume, charge, and cost statistics change with the inclusion of MA claims.

[11] Freed M, et al., *Medicare Advantage in 2021: Enrollment Update and Key Trends*, June 21, 2021. Online: www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends/
[12] Congressional Budget Office (CBO), *Medicare - CBO's March 2020 Baseline as of March 6, 2020*, Washington (DC): CBO, March 19, 2020. Online: https://www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf

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In the same section as noted previously, CMS states:

> *To inform decision making, we are also looking for feedback on how to mitigate any unintended negative payment impacts to providers serving patients with rare diseases or conditions that are represented by low volumes in our claims data. In particular, we are interested in hearing the perspectives of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. We also seek comments on how factors such as hospital size and type might impact a hospital's ability to develop protocols to better address these conditions. We will take commenters' feedback into consideration in future policy development.*

The ASTCT commends CMS for specifically seeking feedback from certain types of facilities that may be disproportionately impacted by treating rare diseases, conditions, and patient populations. As mentioned, ASTCT members treat relatively small numbers of patients with rare diseases in specialized hospitals across the country. While we understand and support CMS' focus on averaging in general, we note that hospitals consider revenue and expense on a *departmental scale*. Service lines are evaluated individually for their financial viability and those departments with a high percentage of losses will face intensive scrutiny every time a request to utilize a high-dollar therapy is made by the clinical team. Clinical teams and service lines that take a significant loss on the provision of each administration of a high-dollar therapy to rare disease populations (such as those CMS notes in the proposed rule) may be viewed by their administration as financially unsustainable. In short, the macroeconomics perspective from which CMS operates the general tenants of the IPPS system no longer matches up with the microeconomics of the hospital.

For these reasons, we encourage CMS to continue examining ways to support those areas of clinical medicine that are particularly affected by the inpatient provision of high-dollar therapies to limited numbers of patients.

Social Determinants of Health

The ASTCT greatly appreciates CMS' attention to better capturing information on the issues that may affect the outcomes and costs associated with treating patients from varying sociodemographic backgrounds. The ASTCT, in conjunction with the National Marrow Donor Program (NMDP), is dedicating time and resources to understanding how social determinants of health create barriers to hematopoietic stem cell transplantation. We are conducting a joint conference in July 2022 and will share findings pertinent to IPPS in future rule-making cycles. Again, we appreciate the inclusion of this RFI in the proposed rule and look forward to further discussion on this topic.

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General IPPS Commentary

Operating Room vs. Non-Operating Room Split

We reiterate our perspective that the use of an OR during an inpatient stay is no longer a harbinger of either clinical complexity or resource use intensity. As demonstrated by the Public Health Emergency (PHE), many of the most clinically complex episodes of care happen outside of the OR.

The ASTCT appreciates CMS' recognition in the proposed rule of the need to revisit the resource use assumptions associated with various types of procedures similar to the historic and current use of OR and non-operating room (non-OR) distinctions in MS-DRG groupings. As CMS acknowledges, recent changes in medical practice show that significant resource use occurs with different non-OR therapies. In its discussion of this issue, CMS states "[w]*hile we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10."*

As a professional organization representing physicians who utilize SCT, CAR-T and other novel cell and gene therapies, we strongly agree with this sentiment. While these therapies are not classified as OR procedures, they are extremely complex and resource-intensive—akin to what OR procedures represented in the past and even exceeding them.

The ASTCT's comment letter on the FY 2018 IPPS Proposed Rule discussed this issue in the context of CMS' proposal to reclassify multiple autologous and allogeneic stem cell transplant ICD-10-PCS codes from OR to non-OR status. We acknowledged that transplant cases are not OR procedures, but that the pre-MDC designation of the transplant MS-DRGs, alongside solid organ transplants and other specialized procedures, remained appropriate and critical to providers. Our point was that, given the implications for grouping of OR and non-OR procedures under the current system, the reclassification of the procedure codes would have deleterious effects on appropriate rate-setting, data collection, and reimbursement.

Therefore, we are glad to see that CMS is reconsidering the breakdown between OR and non-OR procedures as a structural division. We reiterate the fact that therapeutic interventions such as transplants or novel cell and gene therapies have similar or greater resource utilization and complexity as OR procedures but are not OR procedures in and of themselves.

As part of the broader and continuing conversation about future MS-DRG groups for these therapies, **we encourage CMS to consider how other factors that influence resource utilization could be considered at a level similar to OR and non-OR designations**.

Our prior suggestion of utilizing multiple MS-DRGs—one for clinical care costs and one for product costs—would follow this logic. Another suggestion is to consider dividing the current OR/non-OR categories into two additional sub-categories. For example, sub-categories of non-OR low-cost and non-OR high-cost (where cellular immunotherapies like CAR-T would reside) and OR low-cost and OR high-cost MS-DRGs. There are likely many more ideas for addressing this

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issue that the broader stakeholder community could share during Town Halls or Listening Sessions.

CMS could analyze several factors, such as whether certain procedures and therapies make up a substantial percentage of the costs within particular MS-DRGs and whether:

- there is an average amount of cost within the relative weight of an MS-DRG that represents significant resource utilization and complexity; and
- certain types of pharmacy costs, or therapies such as radiation therapy, demonstrate higher cost such that they should be considered similar to an OR procedure.

We recommend that CMS factor these considerations into its analysis, host a listening session with stakeholders, and release the results of its review in future rulemaking.

CMS Relative Weight, Wage Index, and Fixed Loss Outlier Threshold Proposals

1. **Rate-setting Methodology:** The ASTCT appreciates CMS' thoughtful consideration of how to move forward with rate-setting in light of the unusual claims data patterns associated with the COVID-19 PHE. We support CMS' proposal to transition back to using claims data from two fiscal years prior to the upcoming fiscal year. We also support the agency's proposal to modify its usual rate-setting methodology to account for the anticipated decline in COVID-19 hospitalizations in FY 2023. Specifically, CMS' proposal to compute MS–DRG relative weights for FY 2023 by using a 50/50 blended average of relative weights calculated with and without COVID–19 cases using the FY 2021 data seems reasonable. We support CMS' proposal to use 50 percent of the relative weights calculated using all applicable cases and 50 percent of the relative weights calculated without the COVID–19 cases; this approach reduces, but does not fully remove, the effect of COVID–19 cases on relative weights for FY 2023.

2. **Wage Index Reduction Cap:** We appreciate and support CMS' proposal to implement a five percent permanent cap by which a hospital's wage index cannot decrease from one fiscal year to the next.

3. **Relative Weight Reduction Cap**: We appreciate and support CMS' proposal to implement a 10 percent permanent cap on decreases in an MS-DRG relative weight from one fiscal year to the next.

4. **Fixed Loss Outlier Threshold Increase**: The ASTCT is concerned with the substantial (more than 50%) increase in the proposed FY 2023 Outlier Fixed Loss Threshold and asks CMS to further mitigate this increase for the upcoming fiscal year.

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New Technology Add-On Payments for New Services and Technologies

The ASTCT generally does not comment on specific drugs or services being considered for new technology add-on payment (NTAP) unless the consideration pertains to an evaluation criterion and/or payment-associated issue that affects the broader issue of NTAP decision-making and/or payment methodology. The ASTCT is interested in the method and manner in which NTAP payments are calculated, triggered and paid; as such, we offer the following points of commentary.

Situations in which two drugs or biologics with NTAP are utilized

In the FY 2023 proposed rule, there are several therapies—maribavir, narsoplimab, and treosulfan—which could be utilized in varying combinations during the course of a single inpatient allogeneic stem cell transplant episode of care. While it has been historically unusual for hospitals to use two or more drugs or biologics having NTAP status during a single inpatient stay, innovations in the cell and gene therapy space, and the larger field of oncology, may make this a more common occurrence going forward.

Hospitals and other stakeholders may be unfamiliar with how reimbursement for a stay utilizing two or more NTAP therapies will be calculated. The ASTCT has received several questions this scenario; thus, we respectfully request that CMS provide an example of such a calculation in the final rule.

Transition to use of NDC codes for NTAP payment purposes

CMS proposes to begin identifying NTAP cases that involve the administration of a therapeutic agent, like a drug or biologic, by the National Drug Codes (NDCs) assigned to the product by the FDA, rather than a product-specific Section X New Technology ICD-10-PCS codes.

The ASTCT previously provided comments to CMS that using NDC codes may be a useful approach to identifying the use of therapies with NTAP status, rather than creating new Section X codes for this purpose, since coders do not typically assign ICD-10-PCS codes for drug administration for inpatient cases. This suggestion was made with the perspective that the coding burden is expected to grow along with the increasing number of cell and gene therapy approvals. We remain concerned that an important portion of payment for hospitals is dependent on additional and non-standard coding practices, i.e., seeking individual Section X codes for a relatively small subset of therapeutics.

We are grateful to CMS for listening to stakeholder feedback and putting this proposal forward. We discussed CMS' proposal with our members and learned that they have many questions about implementation and existing hospital resources. These questions must be addressed prior to finalization and operationalization of the switch to using NDCs instead of ICD-10-PCS codes.

Given the concerns raised by our membership, we request that CMS not finalize implementation in FY 2023 as proposed. Instead, we ask CMS to consider this switch as part of broader future

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improvements expected for reporting institutional claims.

Some hospitals already have systems that would provide an automated method of capturing NDC codes on inpatient claims. Other facilities, however, will face new and laborious manual processes despite reporting NDCs on certain outpatient claims. This burden would also come at a time when our members and their associated hospitals continue to address resource and staffing constraints resulting from the COVID-19 PHE. As such, implementation of this new process at this time is likely to result in more burden and increased potential for missed NTAP payments than the current usage of Section X codes.

Until all hospitals are required to address a number of other systemic technical and informational technology resource issues and all HIPAA-covered entities are required to accept NDC codes on inpatient claims, we do not believe CMS should move forward with its proposal.

Instead, we ask that CMS assemble a Technical Advisory Group to consider this transition and analyze these and other issues before moving ahead with using NDC instead of ICD-10-PCS codes for purposes of NTAP payment:

1. CMS' intent for hospitals to report NDCs for all drugs/biologics vs. only those qualifying for NTAP;
2. The potential for claim line limits to be reached if multiple drugs/biologics are reported on one claim;
3. The burden on hospitals if NDC reporting for inpatients is a process only utilized with Medicare rather than all payers;
4. The anticipated FDA transition to 16-digit NDC numbers (vs. 11-digit today) and the modifications needed to the 837I/UB-04 that it necessitates;
5. Clarification on the drug unit reporting when NDCs are reported on claims;
6. Description of how CMS would prioritize, read, and make reported NDCs available for stakeholder analysis (e.g., would CMS publish all NDCs reported in the MedPAR files); and
7. Alignment with timing for U.S. implementation of ICD-11.

Public posting of NTAP applications

CMS proposes to begin online public posting of NTAP applications in alignment with the FY 2024 application cycle. CMS cites an interest in increasing transparency and stakeholder engagement and reducing the potential for errors during the summarization process.

The ASTCT generally supports initiatives to make information transparent to all stakeholders, including the non-confidential portions of NTAP applications. We ask that CMS consider the following suggestions, however, before finalizing a revised process:

1. Make application materials available in advance of the rule issuance, if possible, as stakeholders will need more time to directly read and review materials than what reading CMS' summaries currently requires;

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2. Devise a way to utilize small summaries and/or clearly refer to portions of the materials when asking for stakeholder input in the rule, as the source material for specific issues of concern may be unclear to the general reader.

CMS notes that this change would:

> *...also would streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the applications have been increasing over time. That is, by making the applications available to the public online, we would afford more time for CMS to process and analyze the supporting data and evidence rather than reiterate parts of the application in the rule.*

We acknowledge and support CMS in its attempts to streamline and repurpose staff hours in relation to the processing and analysis of NTAP applications. If the proposal to streamline the application analysis and preparation process is finalized and the burden on CMS staff is reduced in the way CMS anticipates, ASTCT asks CMS to reconsider its ability to process NTAP applications twice a year utilizing this new methodology.[13] A modification to the once annual NTAP cycle would allow hospitals providing innovative therapies to begin receiving additional funds necessary to offset their costs in alignment with when the therapy becomes available, instead of needing to wait up to 15 months, depending on the time of approval of the therapy.

Proposed Changes to the Medicare Code Editor

CMS is considering removal of national Medicare Code Editor (MCE) edits and has proposed to conduct a review to identify duplicate edits between the national MCE and other claims processing systems, such as those utilized by MACs. MACs must follow National Coverage Determination (NCD) criteria, but may implement their own edits in addition to the MCE.

The ASTCT believes that CMS should retain the national MCE, which edits claims for covered and non-covered procedures, as MACs systems may not be as current as the National MCE. Reliance solely on MAC claims processing systems may result in hospitals facing additional burden related to unnecessary denials and appeals activity. The national MCE plays an important role in national standardization of coverage requirements and ASTCT asks that CMS retain the system as is.

Significant Cost Determinations Create Incentives for Medicare Advantage

A National Coverage Analysis (NCA) process was begun for autologous CAR-T therapy on the basis of a United Healthcare request that cited the fact that high product costs and promising, but limited, clinical evidence created financial risks for MA contractors.[14] The ASTCT notes that most new cell and gene therapies will receive FDA approval with relatively limited data on efficacy and durability, given their positive effects on intractable and very severe illnesses that lack other treatment options.

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[13] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28355.

[14] UnitedHealthcare, *Formal Request for National Coverage Determination for CAR-T Therapies*, February 22, 2018. Online: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id291.pdf

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If the result of an NCA process is an affirmative National Coverage Determination (NCD) and the product or service is deemed to be a Significant Cost, cases utilizing the product or service revert to being paid for by FFS Medicare until MA providers can appropriately adjust their annual bids. This creates a financial incentive for MA plans to request an NCA for new high-cost therapies not previously covered by other NCDs, such as many of the anticipated cell and gene therapies, as they will be able to set aside financial responsibility for these therapies for a period of time.

Because of the financial incentives that link between NCDs and Significant Cost Determinations creates, the ASTCT believes it is very likely that MA providers will continue to request NCAs for new cell and gene therapy approvals. The NCA processes create substantial unfunded burdens for providers as they seek to address CMS' questions and creates coverage uncertainty during the NCA process.

The ASTCT recommends that CMS seek input on ways to avoid or streamline the NCA process for cell and gene therapies while collaborating with MA plans to address the increased costs associated with these therapies that may not be accounted for in their annual payment amounts at the time of product approval.

Conclusion

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

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Appendix A: Technical Topics

As mentioned in the preamble of this letter, the ASTCT would like to provide CMS with technical suggestions and feedback that may help optimize the methodologies that the agency has implemented for MS-DRG 018. We recognize that recommendations such as these take time and resources to evaluate but believe that this investment is worthwhile in order to improve CMS' systems, reduce inconsistency in the data available to the agency, and minimize provider burden.

Use of Multiple MS-DRGs for Cell and Gene Therapies

The ASTCT's prior request for CMS to consider a potential framework for multiple MS-DRGs—one for patient care costs and one for product costs—was made with expected permutations in care complexity, length of stay, surgical and non-surgical delivery methods, and bands of product costs in mind. The use of these therapies will, most likely, not reach the volume thresholds CMS lays out for the creation of new MS-DRGs or splitting existing ones for many years. The risk of grouping all of these therapies into one single MS-DRG or, conversely, distributing them across a number of existing MS-DRGs that do not reflect the costs associated with product acquisition and administration of the therapies will create significant access barriers for Medicare beneficiaries.

We offer additional commentary and suggestions for these issues in the Rare Disease Request for Information section earlier in this letter. Our overarching point is that because of the differences in therapies, CMS engagement with stakeholders through Town Halls and listening sessions is absolutely critical.

Improve Reporting Accuracy for CAR-T cases within MS-DRG 018

We strongly believe that the more complete and accurate CMS' data are for the costs of cell and gene therapy, the better the agency's rate-setting processes will be. CMS also appears to be interested in gaining a better understanding of the charge variation and the costs of these therapies, given that CMS stated multiple times in the rule, for example that "*the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy*."[15]

The ASTCT agrees that it is important to understand the variability seen in the data. More importantly, it is crucial to have a clear picture of actual product acquisition cost (vs. only billed product charges) and the separate ability to understand the cost of other services associated with providing the cell therapy, such as cell collection, cell processing, and cell administration. Our suggestions for achieving the desired level of transparency are as follows:

[15] Centers for Medicare and Medicaid Services (CMS), "FY 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule," *Federal Register*, 2022; 87(90): 28252.

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Standardize reporting for CAR-T cell collection and cell processing

CMS currently allows hospitals options for the reporting of charges for cell collection and cell processing associated with the manufacturing of the CAR-T product.[16] The ASTCT suggests that CMS simplify and clarify reporting instructions for cell collection and cell processing. Doing so will eliminate inconsistencies in reporting between providers and decrease provider burden associated with manual processes required to hold outpatient cell collection charges and move them to the inpatient claim.

The ASTCT commented in response to the FY 2021 IPPS proposed rule that the practice of bringing outpatient charges over to the inpatient bill when occurring more than three days prior (or one day prior for PPS-exempt providers) is problematic. The ASTCT has repeatedly requested that CMS correct the billing rules that instruct hospitals to put cell collection and processing charges occurring prior to an inpatient stay on inpatient claims—especially since these services occur prior to the 3-day window and would, thus, impact the costs in IPPS data. Our understanding is that the three-day payment window cannot be expanded without legislation; this was discussed in detail in the 2014 report by the Office of Inspector General.[17] This is why our members remain concerned about CMS' continued instruction to allow such outpatient charges to appear on inpatient claims. The ASTCT feels that these non-standard instructions create the risk that claims data for revenue code 0891 could include inappropriate outpatient Part B costs, which could lead to inaccurate calculations of cost for MedPAR data used to generate the relative weights for Part A IPPS payments.

Continuation of this atypical billing instruction also complicates stakeholders' and CMS' ability to understand the low charges reported in revenue code 0891. We recommend that CMS allow hospitals to report all charges following typical IPPS and OPPS rules and for outpatient claims, to bundle or package or set the status indicator to "N." This change will also ensure that outpatient costs are not included in MS-DRG 018.

If CMS is interested in reducing variability in CAR-T therapy charges, then the agency should remove the billing option that allows providers to include outpatient services that occur prior to three days before the inpatient admission on the IPPS inpatient claim. Another way to understand the actual cost of the CAR-T biologic is for hospitals to report their actual costs on the claim using specific value codes finalized by the NUBC; that is, value code 86 for cell therapy and value code 90 for gene therapy acquisition costs.

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[16] Medicare Learning Network (MLN), *Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions, Special Edition Article 19009*, Baltimore (MD): CMS, March 17, 2022. Online: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19009.pdf.

[17] Office of the Inspector General (OIG), *Medicate and Beneficiaries Could Realize Substantial Savings if the Drug Window were Expanded (OEI-05-12-00480)*, Washington (DC): OIG, February 2014.

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Clarify cost reporting instructions and create a dedicated cost center

The ASTCT requests that CMS clarify the type of statistics that are preferred in order to allocate direct department expense and other administrative and general expense for CAR-T services that should be billed with revenue codes 0871-0874 to cost report line 78. Furthermore, CMS has not previously used a standard cost report line for informational purposes only, so it is important that CMS address how expense and revenue for CAR-T services will continue to be allowed as final hospital expense flows through to the worksheet E series.

CMS should consider creating a dedicated cost center line that only captures cell and gene therapy product cost information. This will enable the agency to create a 20th cost center for these types of biologics that is separate from the drug/pharmacy cost center currently used to reduce billed charges to cost for rate-setting. The ASTCT previously recommended this to CMS and continues to believe in its utility. CMS raises this issue in relation to two NTAP applications that both used an applicant-calculated CCR. Specifically, on pages 28222 and 28252, CMS states, "*the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy, and we are continuing to consider the use of this submitted cost data for purposes of calculating a CAR T-cell CCR for use in the applicant's cost analyses given this potential for variability*." If CMS were to implement a 20th cost center, the same set of information would be available for CMS for rate-setting and NTAP applicants to utilize in their cost criteria evaluation.

Use of Condition Code 90 to Report CAR-T Expanded Access Cases

CMS issued transmittal 10571 (MLN Matters article MM11879 Revised on January 15, 2021), which explained to providers the method for billing claims to Medicare for CAR-T therapy cases provided under an expanded access protocol, and CAR-T cases where the patient is enrolled in a clinical trial, but the CAR-T product itself is not under investigation, and the hospital incurs an acquisition cost for the CAR-T product. CMS states that in the remarks field on the claim, hospitals are to include language identifying a CAR-T case as an expanded access case or non-product clinical trial case in order to receive appropriate MS-DRG 018 reimbursement.

The ASTCT requests that CMS consider allowing hospitals to utilize the expanded access condition code 90 instead of the remarks field for reporting these types of cases. It is our understanding that MACs manually fill in a condition code for the expanded access CAR-T claims, based on the information provided by the hospital in the remarks field. Allowing providers to input this information directly on claims would remove a layer of manual work on behalf of the MACs and reduce the potential if inadvertent errors.

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Request for Charging Practice Guidance in Claims Processing Manual(s)

ASTCT is grateful to CMS for reiterating in the last two IPPS Final Rules that "*there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs.*"[18] This aligns with the charging guidance that CMS provides for devices in Chapter 4 of the Medicare Claims Processing Manual (Section 60.4.2, page 82):[19]

> *Note that payment for pass-through devices is based on the charge on the individual bill, converted to cost by application of a hospital-specific cost-to-charge ratio, and subject (in some instances) to a reduction that offsets the cost of similar devices already included in the APC payment rate for the associated procedure.*

Just as CMS provides device charging guidance in the Manual, the ASTCT encourages CMS to do the same for drug charging. We request CMS' clarification on this issue because we continue to hear provider concerns that "high charges," even those that are consistent with their overall CCRs, could garner scrutiny from the OIG, patients, and the media, particularly during a time of increased focus on price transparency and drug pricing issues. These concerns remain widely prevalent, despite the fact that providers' billed charges have no bearing on final patient liability.

Hospital mark-up practices for new technologies must reflect a four- or five-fold increase over actual costs, on average, in order to trigger maximum NTAP payment. This means that a $400,000 product could be listed in a hospital's charge-description master (CDM) at between $1.6-$2.0 million dollars—or even more, depending on the hospital's specific CCR.

The ASTCT continues to diligently educate hospitals about CMS' guidance on setting charges appropriately and in accordance with their CCRs. Yet, we also continue to hear hospitals state that they fear negative repercussions for setting what may appear to be grossly high charges, despite the charges being set in accordance with CMS' guidance, and thus choose not to do so, leaving NTAP and outlier dollars on the table. This reluctance on the part of individual providers to adjust their charges appropriately also negatively impacts future payment rates for all hospitals.

CMS sets future payment rates by estimating case costs from provider's billed charges using national CCRs. Given that many providers fail to charge appropriately, in conjunction with CMS' standardization process, the agency ends up computing an average case cost that is far lower than the acquisition cost providers pay for the current cell therapies assigned to MS-DRG 018. This results in a highly distorted relative weight for MS-DRG 018 that has a large negative impact on *all* hospitals, including the ones that *do* charge consistent with their CCRs.

[18] Centers for Medicare and Medicaid Services (CMS), "FY 2022 Inpatient Prospective Payment System (IPPS) Final Rule," *Federal Register,* 2020; 85(182): 58432; Centers for Medicare and Medicaid Services (CMS), "FY 2022 Inpatient Prospective Payment System (IPPS) Final Rule," *Federal Register,* 2020; 86(154): 44774.
[19] Centers for Medicare and Medicaid Services (CMS), "FY 2022 Inpatient Prospective Payment System (IPPS) Final Rule," *Federal Register,* 2021; 86(154): 44965.

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The ASTCT requests that CMS **formalize its guidance on setting charges in accordance with CCRs for high-cost therapies by including Sections 2203 and 2202.4 from the Provider Reimbursement Manual, shown below, in the Claims Processing manual**. As stated above, this would be similar to what CMS previously did for devices in Chapter 4 of the Medicare Claims Processing Manual (Section 60.4.2, page 82).

Specifically, the following sections are the ones that we request CMS to include in the Claims Processing Manual:

- Section 2203 of the Provider Reimbursement Manual: *[S]o that its charges may be allowable for use in apportioning costs under the program, each facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing the services. While the Medicare program cannot dictate to a provider what its charges or charge structure may be, the program may determine whether or not the charges are allowable for use in apportioning costs under the program."*
- Section 2202.4 of the PRM1: "*...the charge must be recorded at the same gross value for all patients receiving the same service or product, before contractual discounts and deductions are applied…."*

Furthermore, we request CMS to explain that providers can take a pre-billing or post-billing contractual adjustment for commercial payers, so long as the gross charge in the hospital CDM equates to what is posted in the patient accounting system for all patient accounts. This information will be particularly useful for hospital staff who are less familiar with citations from the Provider Reimbursement Manual and the cost reporting processes, yet are responsible for setting up charges and billing, and therefore regularly turn to the Claims Processing Manual.

Additionally, the ASTCT believes that CMS should clarify that the definition of charges is applicable to all hospitals, irrespective of how they are paid by CMS. We have heard from several PPS-hospitals that they believe this definition is no longer applicable to them as it pre-dates the prospective payment systems. Our understanding is that it does apply; therefore, clarification from CMS that it remains applicable to all hospitals, PPS and otherwise, would be welcome.

We appreciate CMS' consideration of these Claims Processing Manual addition requests as we strongly believe the inclusion of these definitions and their application will increase hospitals' understanding about setting their charges in accordance with their CCRs, even for high-cost therapies like CAR-T therapy, despite the optics of doing so. Additionally, it will ensure that all hospitals, including hospitals that become certified in the future, have an evergreen reference to refer to for this requirement, in addition to CMS' language in the IPPS final rules for FY 2021 and FY 2022.

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