



American Society for
Transplantation and Cellular Therapy

June 25, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the provisions affecting our members in the proposed rule governing the Fiscal Year (FY) 2022 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals.

ASTCT is a professional membership association of more than 2,600 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publications, and clinical standards. The clinical teams in our society 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.

As an overall comment on the FY 2022 IPPS rule, we want to thank CMS for their thoughtful consideration throughout the rule for the impact of the COVID-19 Public Health Emergency (PHE) on hospitals. We feel this consideration is evident through the number of proposals in this rule that consider the influence of the pandemic on everything from quality reporting programs to the data utilized for rate-setting.

Thank you for the opportunity to provide comments on the FY 2022 IPPS proposed rule. ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions you may have. Please contact Alycia Maloney, ASTCT Director of Government Relations, at amaloney@astct.org for any follow up issues.

Sincerely,

A handwritten signature in blue ink, appearing to read "Stella M Davies".

Stella M Davies, MBBS, PhD, MRCP
President, ASTCT



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Comments on Proposed FY 2022 Rate-setting

ASTCT Support for Using FY 2019 Data for FY 2022 Rate-setting

In the FY 2022 rule, CMS discussed how the Public Health Emergency (PHE) had impacted FY 2020 data that would typically be used for rate-setting for FY 2022. The ASTCT appreciates the thoughtfulness and consideration that went into CMS' review and that CMS has proposed to utilize FY 2019 data for FY 2021 rate-setting, because it is more reflective of the typical (non-PHE) hospital utilization and case mix. **The ASTCT agrees with and supports CMS' proposal to use FY 2019 data, over the alternate proposal to use FY 2020 data, for the reasons CMS articulated in the proposed rule.** Additionally, we believe CMS must carefully analyze what data to use for FY 2023 rate-setting as the PHE has continued well into CY 2021 and FY 2021 data might be reflective of the same issues as FY 2020.

Chimeric Antigen Receptor T-Cell (CAR-T) Therapy and MS-DRG 018

The ASTCT encourages CMS to finalize its proposal to use the same rate-setting methodology for MS-DRG 018 in FY 2022 as it established and utilized for FY 2021. This would mean that for FY 2022, clinical trial CAR-T cases (those reporting ICD-10-CM code Z00.6) and non-clinical trial cases with standardized pharmacy charges of less than \$373,000 would continue to be excluded from the calculation of the relative weight. As a result, we understand and support CMS continuing to pay clinical trial or expanded access cases at an adjusted amount using the methodology described in the proposed rule. As CMS states, the inclusion of cases without product acquisition costs would significantly compromise the relative weight calculation of MS-DRG 018. Utilizing separate payment rates for when the provider incurs a product cost and when they do not will result in more accurate and appropriate payment.

CMS noted that it is seeking feedback on its proposal to rename MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other immunotherapies." CMS is proposing to map a trial-stage tumor infiltrating lymphocyte (TIL) product, lifileucel, to MS-DRG 018 beginning in FY 2022 and noted that this name change will make MS-DRG 018 more reflective of the therapies that will be mapped to it now and in the future. ASTCT infers that CMS intends MS-DRG 018 to contain one-time administration of cellular immunotherapies such as CAR-T, Natural Killer (NK) cell, T-cell receptor (TCR) and TIL therapies based on expected similarity in resource utilization.

We support this classification in the short-term but wish to note that the pipeline of cellular, gene and regenerative medicine products is robust and will only continue to expand. CMS should begin planning for a scenario in which multiple MS-DRGs are needed to reflect the diversity in patient care episodes and product-related costs. **As such, ASTCT urges CMS to start a broader conversation about how the MS-DRG system can better accommodate inpatient care episodes utilizing this pipeline of therapies, where the product cost will almost always exceed the cost of patient care.** As an example, the expected introduction of allogeneic, universal and/or "off-the-shelf" products across various cell types should decrease the cost of manufacturing and be reflected in the acquisition costs incurred by hospitals.



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Additionally, we request that CMS provide explicit clarification of the term “immunotherapies” in the final rule and consider utilizing terminology more specific to the subtype of immunotherapy being considered, such as “cellular immunotherapies” or “immune effector cell therapy¹”, as these terms are often used to describe therapies like CAR-T and TILs.

ASTCT has noted that there is confusion and concern amongst stakeholders about what types of inpatient stays could group to MS-DRG 018 given the “other immunotherapies” language. These concerns are based on the perception that any inpatient episode utilizing an immunotherapy (the majority of which are not one-time cellular immunotherapies) could group to MS-DRG 018 and negatively influence rate-setting. **We ask that CMS clarify that MS-DRG 018 is a pre-Major Diagnostic Category (pre-MDC) MS-DRG, which means that the grouper logic is being used to route only pre-specified ICD-10-PCS codes (those listed on page 25095 of the Federal Register document) directly into MS-DRG 018.**

Finally, we request CMS update transmittal 10571 (MLN article MM11879)² alongside the release of the FY 2022 Final Rule. The transmittal currently outlines billing and coding practices specific to reporting clinical trial and expanded access CAR-T cases that group into MS-DRG 018 for purposes of modified payment. **Assuming CMS finalizes the mapping of lifileucel into MS-DRG 018, it should clarify that the same billing and coding protocol applies to non-CAR-T cases, so that appropriate payment and rate-setting adjustments can be made and so that there is not a negative impact to the weight of MS-DRG 018 by including these claims in rate-setting.** As part of the transmittal update, we also recommend CMS use standard transaction code set claim fields, rather than the remarks field, to determine when to pay the full MS-DRG 018 amount versus the reduced amount. Specifically, value code 90 would be used to report cell therapy acquisition cost, value code 87 for gene therapy acquisition cost, condition code 90 for expanded access program, condition code 30 for clinical trial, and the Z00.6 diagnosis code to denote a clinical trial.

If the Pricer would utilize the above-mentioned data, instead of the open text remarks field, to determine whether the modified of full payment amount should be made, we believe that program integrity would be improved alongside a reduction in administrative burden for hospitals.

Request to CMS to Issue Guidance on Provider Charging Practices

In the FY 2021 IPPS Final Rule, CMS twice stated that there is “nothing that precludes hospitals from setting their drug charges consistent with their CCRs.” This clarification was made in response to commenters who raised concerns about providers not charging appropriately for the cost of CAR-T therapy products.

ASTCT is grateful to CMS for this additional clarity, which is consistent with the language CMS has used in the Provider Reimbursement Manual, as it has proven to be helpful for hospital finance teams. However, we continue to hear questions, concerns, and requests for more CMS guidance on

¹ [Immune Effector Cell Standards](#), Foundation for the Accreditation of Cellular Therapy.

² Medicare Learning Network. (2021, January 15). *Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) PPS Changes*. <https://www.cms.gov/files/document/mm11879.pdf>

the topic of charging and the use of cost-to-charge ratio (CCRs) to set appropriate charges for CAR-T therapy and other high-cost cellular immunotherapies.

Our understanding is that providers are concerned that “high charges,” even those consistent with a hospital’s overall CCR, will garner scrutiny from patients, the media, and/or the Office of Inspector General (OIG), particularly during a time of increased focus on price transparency. While CMS and other technical experts who are familiar with CMS’ NTAP, outlier and IPPS rate-setting calculations understand why charges must be set higher than costs, and that patients are typically protected from undue financial burden associated with gross charges, many external stakeholders do not. Many of our provider members continue to have concerns about the appropriateness and utility of charging appropriately so that the future MS-DRG weight will reflect their costs of providing CAR-T therapy.

As a result, to maintain appropriate payment for the future and to ensure that MS-DRG 018 is reflective of average case cost, we strongly urge CMS to respond to the questions we raise below and issue further guidance that explains the importance of appropriate charging practices, so that all stakeholders can understand its impact on NTAP and outlier payments.

1. What Cost-to-Charge (CCR) ratio is most appropriate for providers to use when setting pharmacy charges? The overall hospital CCR, hospital pharmacy CCR, national drug cost center CCR or something else?
2. Why does CMS believe it is important for hospitals to set their charges in accordance with their CCRs, particularly for products that have NTAP status? Does this remain important after the NTAP payment period expires?
3. If setting an appropriate charge for a high-cost therapy would result in every hospital case (e.g., every CAR-T case) receiving an outlier payment, should a hospital be concerned?
4. In the past, has CMS ever determined that a hospital’s charges were not allowable for use in apportioning cost? Are there instructions or guidance issued to the Medicare Administrative Contractors (MACs) that they apply in determining whether charges or a hospital’s charge structure is reasonable and consistently related to cost?

In relation to question one, there is confusion around which CCR to use because CMS uses one CCR (the hospital’s operating CCR) to calculate the per-case cost to determine if an NTAP payment and/or outlier payment should be made but it utilizes a different CCR (the national drug CCR) for rate-setting. The results of charges based on the different CCRs vary significantly in terms of the calculated cost as demonstrated by the following table.

Hospital with a wage index of 1.0 and overall CCR of 0.25	Hospital Charges (assumes product acquisition cost of \$400,000)	Total Case Charges with Product Charge	Estimated Product Cost for Rate Setting
Patient Care Charges	\$228,000	N/A	N/A
CAR-T Product Charge Based on Overall Hospital CCR of 0.25	\$1,600,000	\$1,828,000	\$299,200
CAR-T Product Charge Based on Departmental CCR of 0.30	\$1,333,333	\$1,561,333	\$249,333
CAR-T Product Charge Based on National Drug CCR of 0.187	\$2,139,037	\$2,367,037	\$400,000

Given the variances in the calculated costs in this this illustration, it would be helpful for CMS to issue guidance on the appropriate CCR to utilize when setting charges. In the above example, the only scenario that produces an accurate reflection of product cost for rate-setting purposes is when the hospital bases its charge on the national drug CCR of 0.187.

Regarding question two, we believe that clarity from CMS on why it believes it is important to set charges in accordance with CCRs both during and after any applicable NTAP period would provide important context and referenceable examples for providers who are currently reluctant to charge in accordance with their CCRs for high-cost therapies.

Our third question centers on whether charging practices that appropriately result in outlier payments being generated for every case of a certain type would raise scrutiny from the MACs and/or the Office of the Inspector General (OIG). For certain high-cost therapies like CAR-T, setting a product charge in line with a hospital’s CCR may result in an outlier payment for each inpatient case. While this seems atypical in a payment system based on averages, it is a logical outgrowth of setting charges in accordance with CMS’ instructions as outlined in the Provider Reimbursement Manual. We request clarification from CMS that certain areas of care may result in consistent outlier payments due to the unique associated costs.

Our fourth and last set of questions relates to the following language from 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.”

Given that the Medicare program may determine whether charges are allowable for use in



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apportioning costs, our members are requesting information as to whether CMS has ever determined that a hospital's charges were not allowable for use in apportioning costs. Relatedly, they also want to know if there are instructions or guidance that the MACs would apply in determining whether charges or a hospital's charge structure is "reasonable and consistently related to cost". Because of the importance of a hospital's charge structure for accurate cost reporting, is the Medicare program the only arbiter of what is and is not a compliant hospital charge structure or can the OIG raise questions? This question has been raised several times to us by our members since the expiration of NTAP for the first two CAR-T products.

Our members face additional uncertainty around appropriate charging due to a perceived potential impact on its commercial contracts that contain price limitations. Section 2202.4 of the PRM1 states "...the charge must be recorded at the same gross value for all patients receiving the same service or product, before [emphasis added] contractual discounts and deductions are applied." This language appears to clearly state that providers can reduce or contractually adjust down a gross charge before sending it out on a claim for which contractual discounts would apply. However, many hospitals believe their charge must be the lowest level that their commercial contracts allow for all patient accounts, despite the PRM1 Section 2202.4 definition. Specifically, many hospitals do not believe they can post the gross charge at a level consistent with their CCR on all patient accounts, apply a contractual discount prior to billing (when appropriate) to commercial payers, while billing the gross charge to Medicare patient claims.

It would be helpful for CMS to confirm that applying contractual discounts either before or after billing is consistent with the PRM1 definition of charges to record (i.e., post) the product at the gross price (i.e., the same value) on all patient accounts (inpatient, outpatient, Medicare, Medicaid, or commercial patient accounts).

We sincerely appreciate CMS' consideration of the questions raised above and understand that it is not a usual practice to answer these in a final rule. We hope that CMS will at least consider addressing them generally in the rule and release transmittal guidance that provides greater detail at a later date. CMS is the voice of authority for providers, and clarity on these matters will help our members improve their charging practices and result in more accurate rate-setting.

The ASTCT also appreciates that CMS is seeking input on how future rate-setting could be less reliant on hospital charges. We agree that this is important particularly given the issues we are seeing in the data and the charging concerns raised above. We are spending considerable time identifying and discussing potential solutions which still preserve the ethos of the MS-DRG averaging system and which would pay providers appropriately for the care they deliver to patients. Some of our preliminary ideas are explained in the future rate-setting section that follows later in this letter. We also look forward to an ongoing dialogue with CMS as we continue to develop these and other ideas and consider those proposed by other stakeholders.

MS-DRG 014 and Implementation Efforts for Section 108

As part of the implementation of the provisions in Section 108 for cost-based reimbursement for allogeneic stem cell transplant cell acquisition costs, CMS has proposed excluding donor search



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and cell acquisition charges from the calculation of the relative weight for MS-DRG 014. **The ASTCT agrees with this modification to rate-setting for MS-DRG 014, which will result in the MS-DRG 014 payment representing only patient care costs for allogeneic hematopoietic stem cell transplant.**

As part of finalizing these changes, ASTCT requests that CMS clarify certain questions for stem cell transplant providers. We believe that additional clarification from the agency in the rule or subsequent guidance will help with the successful implementation of cost-based reimbursement for the cell acquisition costs incurred. CMS has stated before that it is developing new cost reporting instructions that may address some of these questions but providing additional explanation in the final rule would be useful and timely for providers.

- Does CMS still want providers to report all donor search and cell acquisition charges utilizing revenue code 0815, as providers were instructed to prior to the passage of Section 108 cost-based reimbursement?
- Since CMS utilizes the charges reported in revenue code 0815 to calculate future interim payments for hospitals, will the impact of not using the revenue code and reporting all charges to Medicare result in a larger payment due to the provider at settlement?
- How will Medicare reimburse hospitals for the donor search and cell acquisition costs that are related to transplants that are cancelled or otherwise uncompleted due to a treatment plan change, patient death, or other complicating factor?
- Does CMS allow both direct and indirect donor search and cell acquisition costs to be captured and reported in cost report line 0077 in the Medicare cost report?

Beyond the questions above, we ask that CMS address the issue of how the removal of cell acquisition charges from the calculation of MS-DRG 014's relative weight will impact Medicare Advantage plans that base their negotiated rates off MS-DRGs. We believe that CMS remarks on this topic in the final rule will help raise awareness of this issue and help providers have discussions with Medicare Advantage plans on separate reimbursement for donor search and cell acquisition costs for allogeneic transplants, since these costs will no longer be covered through MS-DRG 014 payments with the start of FY 2022. **We request that CMS address how Section 108 will change MA payment for allogeneic cell acquisition costs for both in-network and out-of-network cases. We also request that CMS update all its guidance materials and manuals that discuss allogeneic hematopoietic stem cell transplant coding, billing, and reimbursement to reflect all the recent changes around cost reimbursement.** The implementation of Section 108 will have a significant effect on the payment Medicare providers receive for the provision of stem cell transplantation and up-to-date guidance from Medicare is crucial to ensure that providers have the right information to bill CMS correctly.



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Requiring Submission of Value Codes for Donor Information

We request that CMS adopt and instruct transplant centers to report the following value codes approved by the National Uniform Billing Committee (NUBC) for allogeneic HSCT claims effective July 1, 2020:

- **Value code 88:** This value code indicates the number of related donors who were evaluated and is reported on the recipient's transplant claim. A zero is allowed for instances when no related donors were evaluated.
- **Value code 89:** This value code is used to report the total charge amount for both related and unrelated donor services, including charges that were submitted on separate claims. This code would be reported on the recipient's transplant claim.

Concerning value code 89, we understand that Medicare does not allow separate claims for donor acquisition costs but if CMS asked hospitals to report their total charges for donor services in value code 89, it would help verify that all charges associated with CMS' definition of donor search and cell acquisition have been reported, as this amount should match the charges reported on the recipient's claim under revenue code 0815. ASTCT believes the use of these codes is another way to ensure the integrity of the claims data submitted to CMS. We have included more information regarding use of these codes in Appendix B of this comment letter.

New Technology Add-On Payments (NTAP) for FY 2022

The ASTCT is aware that five of the products seeking NTAP approval for FY 2022 are proposed to map to MS-DRG 018. For each of these products, CMS asked for commentary on the eligibility of technologies that would group to MS-DRG 018 to receive NTAP as well. In prior rulemaking documents, CMS noted that there may no longer be a need for NTAP payments for CAR-T products after the creation of MS-DRG 018.

It is the ASTCT's perspective that the subject of assignment to MS-DRG 018 and the granting of NTAP status are separate issues. We request that CMS evaluate each NTAP application for products that would group to MS-DRG 018 in the same manner as for other NTAP applications— if the product meets each of the three criteria: newness, cost, and significant clinical benefit, that it be granted NTAP, and if it fails to meet the criteria, NTAP should be denied.

Furthermore, we believe that that CAR-T is a new field of therapeutic intervention that will encompass a range of innovations for a variety of conditions, including those beyond cancer. That the first two FDA-approved CAR-T products received NTAP status does not necessarily mean that the CAR-T products that are approved later are not also "new" in the context of NTAP or that they will not meet the other NTAP criteria. It will continue to be critically important to evaluate the appropriateness of granting a new product NTAP status via public discussion in the proposed rules, and to determine which factors truly warrant NTAP, in order to keep pace with innovation.

The ASTCT appreciates the significant change CMS made in the FY 2020 rule to increase NTAP



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payments to the lesser of 65% of the cost of the NTAP product or the residual cost of the case. We recognize that this increase to the NTAP product cap was the first modification of the payment amount since the program's creation and that CMS made the change due to its strong belief in the potential for new technologies to dramatically impact the lives of Medicare beneficiaries. This increase in payment rate was and will continue to be extremely important to our provider members, as they incur the full cost of cellular immunotherapy products when acquiring them on behalf of beneficiaries. Despite this historic increase, substantial issues remain with the NTAP program that we believe warrant consideration if the program is to continue to serve its goals of expanding access to new technologies.

The first issue is that of the NTAP application cycle itself. The current structure of requiring FDA approval by July 1 for an upcoming Fiscal Year will continue to be problematic for beneficiary access and for providers interested in utilizing new therapies that are initially mapped to DRGs non-reflective of the cost of product acquisition. Gaining FDA approval in August means that a product may be commercially available for up to 14 months before potentially gaining NTAP status the following October, during which time providers cannot avail themselves of add-on payments.

Given the high product acquisition costs associated with many novel therapies that seek NTAP status, providers face the choice of losing significant amounts of money during a non-NTAP period or delaying provision of new technologies to Medicare beneficiaries until the next fiscal year. The complexity of these novel products means that the FDA approval process is rarely predictable and may require multiple delays to satisfy approval requirements. This uncertainty makes it improbable that a manufacturer will be able to orient their approval process for an approval before July in a particular calendar year. Allowing for more than one approval deadline or allowing for a provisional NTAP approval for applicant products that will likely become FDA-approved during the relevant Fiscal Year would remove a significant financial burden from providers.

Second, the "lesser of" language is problematic given the high prices of novel cell and gene therapies and how providers continue to struggle to set appropriate charges. **For this reason, we recommend that CMS pay the full NTAP capped cost amount for each case, rather than utilizing the "lesser of" framework.** This could help ensure that hospitals are appropriately reimbursed for the cost of the new technology each time that it is provided, even as they work through the internal processes associated with improving their charging practices.

Third, we recommend that CMS consider a further increase to the NTAP payment amount, from 65% to 80%. Providers continue to have no ability to seek price discounts for novel cell and gene therapies, particularly autologous ones, and the loss of 35% of the product acquisition cost can equal tens or hundreds of thousands of dollars in unreimbursed costs for each case. We believe that an increase to the NTAP cap could help ameliorate some of the financial precarities of offering high-cost novel treatments. The ASTCT anticipates the approval of several gene therapies that will likely be priced at more than a million dollars and utilized during an inpatient episode of care over the next few fiscal years and asks CMS to begin consideration of how NTAP payment at the current level will impact the potential of these therapies being made available for beneficiaries.



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Finally, we believe CMS' overall presumption that the volume of new technology cases will be sufficient to cause an appropriate adjustment to the relative weight (or to substantiate a new or split MS-DRG) after 2-3 fiscal years is unlikely for many therapies in the pipeline of cell and gene therapies, particularly those for rare disorders. Those products may only see volumes of dozens of cases annually. We ask CMS to consider ways to bridge the time period between having NTAP status and reverting to the basic MS-DRG and outlier payment structure, such as identifying the need for a new MS-DRG at the time of NTAP status approval and taking steps to have it in place at the point NTAP status expires.

Comments on Future Rate-Setting

Support for Repealing Use of MA Rates for FY 2023 and Future Rate-setting

The ASTCT also supports CMS' proposal to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all its MA organization payers, by MS-DRG, for cost reporting periods ending on or after January 1, 2021. Our understanding is that this data was to be used to develop MS-DRG relative weights for FY 2024. Repealing this data collection requirement will substantially reduce provider burden.

Additionally, we support CMS' proposal to repeal the market-based methodology finalized in last year's rule. Given CMS' proposals to move away from using MA rates as the basis for future rate-setting, the existing rate-setting methodology will remain in place until such time some other alternative methodology or data sources could be used for rate-setting. As current methodology is based on charges reduced to costs using the 19 national CCRs, we remain concerned about charge compression and provider charging practices and the impact charging practices have on the NTAP and outlier calculations within this structure.

Rethinking OR Versus Non-OR MS-DRG Hierarchical Splitting

The ASTCT appreciates CMS' recognition in the proposed rule that there is a need to revisit the resource use assumptions associated with operating room (OR) and non-operating room (non-OR) episodes of care given the changes in ICD-10-PCS and medical practice in recent years. 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 that utilize SCT, CAR-T and other novel cell and gene therapies we strongly agree with this sentiment. These therapies are not classified as OR procedures, yet they are extremely complex and resource intensive.

In ASTCT's comment letter on the FY 2018 IPPS Proposed Rule, we discussed this issue in the context of a proposal to reclassify multiple autologous and allogeneic stem cell transplant ICD-10-PCS codes from operating room to non-operating room status, which would have resulted in effectively reclassifying transplant procedure codes into other MS-DRGs based on unintended consequences on MS-DRG grouper logic. We acknowledged that transplant cases are not operating

room 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 the reclassification of the procedure codes, given the implications for grouping of operating room and non-operating room procedures under the current system, 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 operating room and non-operating room procedures as a structural division. Therapeutic interventions such as transplants or novel cell and gene therapies may have the same or more resource utilization and complexity as operating room 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 examine how other factors influencing resource utilization should be considered at a level similar to the OR and non-OR designation.** One alternative to an OR and non-OR designation that may be appropriate for cell and gene therapies is the creation of separate MS-DRGs that utilize averaging for patient care costs that would be distinct from groupings for average product acquisition costs across a therapeutic category.

MS-DRGs for patient-care costs: The resource utilization associated with patient care costs – separate from product acquisition costs - for inpatient stays must be valued and reimbursed accurately to sustain and expand the clinical programs that provide these novel therapies. Many autologous and allogeneic cellular immunotherapy products (CAR-T, NK, TIL, TCR, iPSC, etc) and *ex vivo* hematopoietic stem cell gene therapies will continue to require a lengthy and complex episode of care for the foreseeable future. These episodes of care may include multiple days of conditioning to prepare the patient to receive the cellular product or graft, the infusion procedure itself, and an extended (10+ day) period of monitoring and support until patients have experienced a clinical response that warrants discharge. While these patients never enter the OR, they require specialized and multidisciplinary care for weeks in some of the most resource-intensive units in the hospital, including the Intensive Care Unit.

As more products come to market, there will be an evolution of the resource-intensity associated with providing the various individual therapies to Medicare beneficiaries – the administration of products with fewer toxicities or decreased conditioning may allow for shorter and less resource-intensive care, while other therapies will continue to require a sustained-resource model. The variation in patient care resources used should be reflected in the cost data submitted to CMS and thus allow CMS to create groupings that represent the average patient care costs across multiple products, enabling the Agency to retain its averaging process and preserving the premise of clinically similar and resource homogenous MS-DRGs.

MS-DRGs for product costs: Our clinicians are not able to influence the costs of the cellular immunotherapy product acquisition. The creation of product-based MS-DRGs would allow CMS to create bands of payment for categories or types of products that would be paid in addition to the patient care cost DRG without agreeing to invoice-based product payment methodology. CMS would have some flexibility in how to create one or more separate payment groups for various products over-time that reflects some form of averaging of either manufacturer reported ASPs or data obtained through Value Code 90.



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Other Factors to Consider for MS-DRG Grouping Logic

To create MS-DRGs for patient care costs, separate from averaged product costs, it will be necessary to understand the level of care, outcomes, and costs associated with the use of particular products. This means CMS must have a mechanism to identify therapeutic drugs and biologics administered to patients on inpatient claims data in order to utilize these other factors in new MS-DRG grouping logic.

Due to the current lack of visibility of drugs on Medicare inpatient claims data, a stakeholder who wishes to track the use of a drug or biologic for Medicare inpatients is primarily left with one option – requesting a new ICD-10-PCS code within the New Technology tables. While these codes suit the purpose, as well as triggering NTAP when applicable, they unnecessarily inflate the number of ICD-10-PCS codes and information on other drugs and biologics used during the inpatient episode remain unavailable for analysis.

We have been considering how drug and biologics information could be collected for inpatient claims. To better understand current requirements for inpatient claims, we reviewed the NUBC manual to determine if there was an existing mechanism for reporting detailed codes for drugs and biologics on inpatient claims. NUBC states the following concerning reporting of HCPCS codes on inpatient claims: *“Required for inpatient claims when an appropriate HCPCS (drugs and biologics only) or HIPPS code exists for this service line item.”*

If we understand this statement from NUBC correctly, it appears that HCPCS codes are already expected, or even required, on inpatient claims for drugs and biologics that have a HCPCS code. ASTCT requests CMS to clarify in the final rule whether they already receive inpatient claims with HCPCS detail in revenue codes 025x, 063x and 089x. It appears that CMS would be consistent with NUBC if it were to clarify to providers that HCPCS detail on drugs and biologics is expected on inpatient claims. CMS could then modify the MedPAR file to include drug and biologic HCPCS detail and use this information to determine if certain drug and biologics or classes of similar drugs and biologics are appropriate as other factors to impact MS-DRG groupings and relative weights. This would enable CMS to consider patient care MS-DRGs and product cost MS-DRGs as described above.

For new drugs and biologics that have not yet been assigned a HCPCS code, the NDC could be reported along with an unlisted drug or biologic HCPCS code in the revenue code description field, per NUBC. Hospital systems are typically set up so that when drug HCPCS code details are provided on the claim, the NDC code for the drug is also provided on the claim. If CMS confirms that it currently receives this data from hospitals, and that it is required per NUBC, it will mean that there is the same level of information on drugs and biologics use available for inpatient encounters as there is for outpatient claims. This would not only enable the study of the use of other factors in MS-DRG splits but could improve the understanding of acute inpatient episodes of care.

Separately, we also request that CMS investigate its criteria that all inpatient claims have expenses in 14 of the 19 cost centers, as the evolution of medicine may mean that fewer cost groups are represented in a growing number of inpatient claims. If such claims are clinically and financially



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accurate, it would be important to include them in future rate-setting.

Comments on Proposals Related to ICD-10 Coding

New Diagnosis Codes

The ASTCT was pleased to learn that the National Center for Health Statistics recently finalized the creation of new diagnosis codes to recognize complications of immune effector cell therapy: three new complications codes (T80.82XA, T80.82XD, and T80.82XS) and codes to recognize the grades of Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). **We appreciate and support CMS' proposal to assign CC status to the diagnosis codes representing higher grades of ICANS.** We feel this is an appropriate recognition of the increased resource utilization and complexity that patients with the higher grades of this complication represent.

General Recommendations to Improve the ICD-10 Coding and Maintenance Committee Process

As with other aspects of coding, the process of updating the ICD-10 coding sets to add codes or appropriately assign codes to the correct locations of the coding set remains challenging for stakeholders to navigate. We anticipate these challenges to only grow as new classes of products continue to develop and as the rate of requested updates increases. Given the importance of the public meetings and discourse on coding changes, we offer the following suggestions and recommendations to CMS, as part of its efforts to improve transparency and efficiency of the ICD-10 Coordination and Maintenance Committee.

First, we recommend that CMS publish all coding change requests publicly, even if those changes are not discussed or accepted for discussion at a particular upcoming public meeting. This would allow requestors to see if there are others who are interested in the same topics and could improve collaboration and consolidation of different requests. We think this public transparency, like how public comments on the IPPS rule are posted, could improve the overall process.

Second, we request that the NCHS and/or CMS consider connecting the requestors making the same or similar requests so that discussions on the proposed coding change(s) can occur jointly. This will improve consensus on any proposals put forward. The agencies could consider creating or hosting a special workgroup to evaluate the coding issue in cases of discord.

Third, we request that CMS provide a rationale to requestors if their request is not accepted for discussion at the upcoming meeting. This will help with requestor planning and learning; depending on the rationale, a requestor may wish to withdraw, edit, or refine their coding change application.

Fourth, given that it is important for presenters and other stakeholders to attend and speak at the public meetings, we request that CMS publish the agenda for the meetings at least three weeks prior and notify requestors that their proposal will be discussed at the meeting at



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least 30 days in advance. This will allow for requestors to ensure that clinicians are able to be present and speak on these topics.

Finally, we were pleased that one of the subjects of discussion at the March 2021 ICD-10 Coordination & Maintenance Committee meeting was to add a second release cycle (April 1) for ICD-10 diagnosis and procedure codes, in addition to the existing October 1 cycle. We appreciate and support the addition of a new release cycle. **We request that CMS finalize this change and provide a timeline for when stakeholders can weigh in on MS-DRG assignments for codes that would be implemented on the April 1st cycle.**

We understand that today there is not an opportunity for stakeholders to comment to the agency about codes discussed at the March ICD-10-PCS meeting, finalized for October 1 implementation, and released alongside the final rule. ASTCT thinks that allowing for additional stakeholder input on MS-DRG assignment for both release cycles would be beneficial. For example, there could be an additional 30-day comment period with the release of the final rule, during which stakeholders could comment on the published MS-DRG assignments for newly released codes that were discussed at the March meeting. Similarly, with the addition of the April 1 release cycle, CMS could implement a 30-day comment period in the fall.

Proposed Changes to Unspecified Codes Severity Level Designation

In this rule, CMS has proposed declassifying approximately 3500 unspecified ICD-10-CM diagnosis codes, meaning that the impacted codes would no longer influence the grouping of a particular case into a Complications or Comorbidities or Major Complicities or Comorbidity MS-DRG. CMS published the full list of the impacted codes in table 6P.2a. This table includes information on volume and other factors relating to these codes. Evaluating this list by volume shows that among the highest-volume diagnosis codes that CMS proposes to declassify are unspecified neoplasm codes. The ASTCT is concerned that CMS' proposal will lead to an increase in administrative burden for physicians through coder queries.

Unspecified code reporting is often a function of factors that are outside of a coder's control, or even those of a physician or hospital. If a patient is admitted to the hospital without prior records, an unspecified code may be all that can be reported. Furthermore, if a physician does have access to prior records where more specificity (such as location or laterality of a neoplasm) was indicated, the physician may not rewrite the specificity in the documentation for a particular encounter. Since existing coding guidelines do not permit coders to code specificity from previous encounters or outside records, unspecified codes are the only option available for reporting, and thus must be used.

Therefore, we believe that improving coding specificity should be a goal that is addressed through modifications and updates to coding guidelines, not through changes to the severity classification of unspecified diagnosis codes. Unspecified code or not, the resource intensity and treatment plan for patients with a neoplasm diagnosis remains the same for a provider. Instead of the proposed change, CMS should consider updates to guidelines that would permit coding specificity from other clinical staff documentation with the physician's confirmation.



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Furthermore, we feel that any change of this magnitude by CMS should not be implemented without giving providers time to restructure physician documentation improvement plans and implement changes. If finalized, we ask that the agency delay implementation by at least two years, if not longer. After the delay, we would also suggest that CMS re-analyze its data to see what improvements in specificity have been made. **We also suggest that CMS consider further analysis before finalization that would include a qualitative review of typical coding practices for inpatient stays associated with the codes it is proposing to declassify.** This would help clarify if the issue is truly with coding, or whether other factors are involved that require intervention, rather than declassifying unspecified codes.

Responding to Request for Information on Health Equity

The ASTCT was pleased to see CMS' request for information on closing of the health equity gap in hospital quality reporting programs. In the rule, CMS stated it was seeking feedback on ways to attain health equity for all patients and sought comments on enhancing hospital-specific reports that stratify measure results by Medicare and Medicaid dual-eligibility and other social risk factors in order to make reporting more comprehensive and actionable, and ways to improve demographic data collection, including a minimum set of data elements to be collected by hospitals at the time of hospital admission.

These are good questions for the agency to ask because it is our belief that any data collection efforts and stratification of measure results cannot serve as a complication or barrier for patients and providers, or it will defeat the purpose of program changes.

In terms of CMS' idea of stratifying measure results for hospital quality programs by Medicare and Medicaid dual eligibility, and other social risk factors, we believe that careful consideration is required in terms of how the "other social risk factors" are quantified and utilized by CMS. As the agency is aware, there are myriad other factors that are not accounted for in dual eligibility, and underserved populations in a geographic area or population may not be underserved in another. Also, dual eligibility as a marker would not capture the risks for patients who are in states that did not expand Medicaid. Therefore, it is important that any stratified measurements are vetted, transparent, and rely on best analytic practices. We are also concerned that stratification by race and ethnicity for each center could run into issues with low reported numbers, thus impacting the accuracy of the data and any comparison between hospitals.

Finally, we wish to address CMS' discussion of collection of risk factors upon hospital admission. We support the collection of risk factors but wonder if collection of the same data at each admission will be the most efficient, patient-focused way to collect this information. It would perhaps be better if this information was obtained by CMS as part of Medicare enrollment and provided through a portal or other common and frequent electronic healthcare transactions. Or, if information on risk factors that was collected from previous admissions could be available to providers through the common working file (CWF), similar to how admission dates are viewable for patients; this would make the information available for subsequent admissions and reduce burden on patients to answer questions at each admission.



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Again, we appreciate the inclusion of this RFI in the proposed rule and look forward to further discussion on this topic.

Conclusion

On 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.

Appendix A: Summarization of ASTCT Recommendations

Below, please find a draft summary of ASTCT’s recommendations on issues relating to proposals in the FY 2022 IPSP Proposed Rule.

Recommendations Related to FY 2022

- **Use FY 2019 data for FY 2021 rate-setting:** FY 2019 data are more reflective of the typical (i.e., non-Public Health Emergency [PHE]) hospital utilization and case-mix and should be used instead of FY 2020 data. We also encourage CMS to carefully analyze data that will be used for FY 2023 rate-setting, given the extensive length of the PHE.
- **Exclude clinical trial cases and cases with standardized pharmacy charges less than \$373,000 from the relative weight development of CAR-T MS-DRG 018:** CMS should continue using the methodology it finalized for FY 2021 for FY 2022 MS-DRG 018 rate-setting. This involves excluding clinical trial cases (those reported with diagnosis code Z00.6) and cases with standardized pharmacy charges less than \$373,000.
- **Pay for clinical trial and expanded access cases assigned to MS-DRG 018 at a lesser amount:** CMS should continue paying for clinical trial cases and expanded access cases in MS-DRG 018 utilizing an adjustor (proposed to remain at 0.17).
- **CMS should clarify what it means by “other immunotherapies” in its proposal to rename MS-DRG 018:** In addition to clarifying what it means by “other immunotherapies” in the name change proposed for MS-DRG 018. CMS should consider using other terminology to rename this DRG, such as “immune effector cells”.
- **Address clinical trial and expanded access case billing for MS-DRG 018 in the FY 2022 Final Rule and update and release a new version of transmittal 10571:** CMS should confirm that the same billing and coding reporting protocol applies to other cases under trial that are assigned or proposed to be assigned to MS-DRG 018, such as lifileucel cases. CMS should also migrate to using standard transaction code set claim fields rather than the remarks field to report this information.
- **Issue guidance on appropriate charging practices utilizing Cost-to-Charge (CCR) ratios:** CMS to provide additional clarity around its statement from the FY 2021 IPPS Final Rule that providers’ have the ability to set charges in line with CCRs, particularly around which CCR is most appropriate to use, and that this methodology of setting charges is appropriate both during and after an NTAP period.

- **Remove donor search and cell acquisition charges from MS-DRG 014 as proposed and respond to operational questions related to the implementation of cost-based reimbursement for donor search and cell acquisition:** Questions related to reporting donor search and cell acquisition charges via revenue code 0815, reimbursement for donor search and cell acquisition costs related to cancelled and/or non-completed transplants, and how direct and indirect donor search and cell acquisition costs are to be captured and reported in the cost report should be addressed.
- **Provide clarification on Section 108’s impact on Medicare Advantage (MA) plans that base their negotiated rates off MS-DRGs and update guidance materials and manuals:** In FY 2022, donor search and cell acquisition costs for all allogeneic stem cell transplants will no longer be included in MS-DRG 014. Therefore, CMS should address how this will impact MA plans and cases.
- **Instruct transplant centers (TCs) to report NUBC-approved value codes for allogeneic stem cell transplant:** The NUBC approved two new codes in 2020 (value codes 88 and 89); CMS should adopt those codes and provide instruction for their use. Doing so will help TCs ensure they are submitting accurate charges and improve the integrity of claims data.
- **Evaluate the MS-DRG assignments for products separate from their NTAP requests and continue improving the NTAP program:** CMS should evaluate NTAP applications independently from any proposed MS-DRG 018 assignments being considered. Additionally, CMS should improve the timing of the NTAP application cycle, remove the “lesser of” language in the NTAP payment formula, and increase the NTAP cap to 80% of product cost.

Recommendations Related to Future Rate-Setting

- **Support repealing the market-based MS-DRG relative weight methodology finalized in the FY 2021 final rule and the reporting of median payer-specific negotiated charges on the Medicare cost report:** MS-DRG relative weights should not be based on median Medicare Advantage rates in the future, nor should providers be required to report median MA rates on hospital cost reports.
- **CMS should find a methodology beyond use of an Operating Room (OR) to assess the resource-intensiveness of a procedure:** The existing hierarchical split methodology based on OR and non-OR as a proxy to gauge resource intensity of different MS-DRGs must be revisited so that other factors are considered, such as the utilization of certain products in a therapeutic class, especially for cell and gene therapies. We ask CMS to clarify their understanding of National Uniform Billing Committee Requirements for reporting HCPCS codes on inpatient claims as part of determining what data the agency might have available to set up new factors for evaluating MS-DRG splits.

Recommendations Related to ICD-10 Coding

- **Finalize “CC” status assignment to diagnosis codes representing higher grades of Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS):** Now that the National Center for Health Statistics has finalized new diagnosis codes to recognize ICANS, it is appropriate for CMS to assign CC status to the diagnosis codes representing higher grades of ICANS, in recognition of increased resource utilization and complexity.
- **Do not declassify the CC or MCC status of unspecified ICD-10-CM diagnosis codes:** There are reasons that unspecified diagnosis codes are used, and their use does not diminish the resources required to care for patients. CMS can meet its goal to improve coding specificity through other mechanisms, such as working with the cooperating parties to update coding guidelines to allow coding specificity from other clinical staff documentation. If CMS does finalize this proposal, we recommend delaying implementation by at least two years.
- **Finalize a second release cycle for ICD-10 diagnosis and procedure coding and create a mechanism to allow public comment on MS-DRG assignments for codes released outside of the IPPS rulemaking cycle:** Having a second code release cycle in April will be a great benefit to providers, researchers, and others. CMS should also release a timeline indicating the dates by which stakeholders can provide feedback on MS-DRG assignments for codes to be implemented as part of the April release cycle. The agency should provide additional opportunities for stakeholders to comment about codes under discussion.
- **Improve transparency of coding change requests submitted to the ICD-10 Coordination and Maintenance Committee:** There are a number of changes that should be made to improve the overall process when stakeholders are seeking new diagnosis or procedure codes.

Response to CMS’ Request for Information on Health Equity

- **The ASTCT responded to CMS’ request for information closing the health equity gap in hospital quality program reporting.** We thanked CMS for addressing this topic and soliciting comment and focused on raising questions related to CMS discussion of stratifying measure results by dual eligibility and other social factors, and collection of race and ethnicity data and risk factors on hospital admission, giving a suggestion on a potential alternative for data collection.