Summary of Comments and ASTCT’s Recommendations

Below, please find a draft summary of the American Society for Transplantation and Cellular Therapy’s (ASTCT’s) recommendations on issues relating to proposals in the FY 2022 Inpatient Prospective Payment System (IPPS) 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 Centers for Medicare & Medicaid Services (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 the agency 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 the agency 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 should 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 with respect to which CCR is the 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: CMS should address 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.

- 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/cases.

- Instruct transplant centers (TCs) to report NUBC-approved value codes for allogeneic stem cell transplant: The National Uniform Billing Committee (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 not only help TCs ensure they are submitting accurate charges but also 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 New Technology Add-on Payments (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 Medicare Advantage rates on hospital cost reports.

- Identify 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. CMS should clarify its understanding of National Uniform Billing Committee (NUBC) 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 thank CMS for addressing this topic and soliciting comment. The ASTCT 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, and provided a suggested potential alternative for data collection.