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July 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735-P
P.O. Box 8016
Baltimore, MD 21244-8016

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov.

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1735-P)

Dear Administrator Verma,

The American Society of Hematology (ASH) is pleased to offer comments on the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates. We appreciate the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on the provisions affecting our members.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

Specifically, ASH provides comments on the following provisions:

1. Chimeric Antigen Receptor T-cell (CAR-T) Therapies
2. Proposed Changes to Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

Chimeric Antigen Receptor T-Cell (CAR-T) Therapies

ASH thanks CMS for the proposals included in the IPPS proposed rule related to reimbursement for chimeric antigen receptor T-cell (CAR-T) therapy. ASH's members are at the forefront of this therapy, conducting research and providing this potentially curative treatment to patients with certain types of lymphoma and leukemia. Patients receiving CAR-T therapy have typically exhausted all other treatments, including chemotherapy, radiation, or stem cell transplant. CAR-T therapy represents a potentially

life-saving option to patients whose care needs are currently unmet by existing therapeutics. ASH's main priority is protecting and improving appropriate patient access to this potentially curative therapy.

ASH's comments regarding the proposals related to CAR-T therapy are outlined below.

Proposed New MS-DRG 018

In the Society's comments on the FY2020 IPPS proposed rule and in a letter jointly sent by ASH and American Society for Transplantation and Cellular Therapy (ASTCT) earlier this year, ASH requested that CMS extend the New Technology Add-on Payment (NTAP) for the approved CAR-T products through FY2021 in order to allow for more time to collect data to create an appropriate MS-DRG for CAR-T. While the Society remains concerned that more and better data are needed to determine an appropriate weight for the new MS-DRG, ASH supports the steps taken by CMS in its proposed new MS-DRG 018, Chimeric Antigen Receptor (CAR) T-cell Immunotherapy. ASH also recognizes the significance of and is supportive of the steps CMS is proposing to help ensure that physicians and institutions are being reimbursed for the care provided by excluding clinical trial cases and claims with pharmacy charges less than $373,000 when calculating the weight of this new proposed MS-DRG.

ASH does remain concerned that even with the new proposed MS-DRG, institutions will move to provide CAR-T therapy in the outpatient setting. As the agency knows, patients eligible to receive CAR-T therapy are fragile and ASH feels that the inpatient setting is still the safest and best setting to treat most patients with these therapies. ASH urges CMS to continue to analyze claims and recognize the significant costs of these patients when admitted to the hospital for CAR-T treatment. ASH makes the following recommendations that we believe will better recognize these high costs.

First, ASH urges CMS to assign complications or comorbidities (CC) and major complications or comorbidities (MCC) status to the new cytokine release syndrome (CRS) ICD-10 diagnosis codes that will go into effect October 1, 2020. Specifically, ASH requests that ICD-10 code D89.832 be considered a CC and D89.833 – D89.835 be considered an MCC. CRS is the most common side effect experienced by patients receiving CAR-T therapy, which can vary dramatically from mild to moderate to severe, life-threatening reactions and in some cases, death. Other patients experience both CRS and Immune effector cell-associated neurotoxicity syndrome (ICANS) – there are not yet diagnosis codes for ICANS, but we hope to get these approved later this year so that they can also be added to the CC and MCC lists. These complications often result in patients having to extend their hospital stay in the intensive care unit (ICU), which significantly increases their cost of care. The assignment of CC and MCC status to the CRS codes will enable patients that are admitted to the hospital following outpatient treatment of CAR-T, who develop CRS, to be assigned to the most appropriate MS-DRG.

ASH urges CMS to consider further subdividing MS-DRG 018 into separate MS-DRGs that account for the higher costs for those who develop CRS. Every patient receiving CAR-T reacts differently – this could be dependent on severity of the disease, underlying conditions, and/or which CAR-T product was used – therefore, the patient care costs of individuals receiving CAR-T therapy can vary widely and CC/MCC status for CAR-T patients with CRS could help to account for these variations in cost.

Second, ASH recommends that CMS use claims that utilize the pharmacy revenue code 250 and revenue code 0891, which is specific to CAR-T, when determining the weight of MS-DRG 018 in the final rule.[1] According to our analysis CMS only used claims with revenue code 250. We believe that this has resulted in an under-evaluation of the cost of CAR-T cases. By using both sets of claims the MS-DRG 018 will be more appropriately weighted. ASH is excited that hematology continues to be at the forefront of CAR-T therapies that dominate the pipeline and wants to ensure continued patient access. ASH supports that all CAR-T hospital admissions be included in the new MS-DRG 018.

[1] Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions. MLN Matters. May 28, 2019. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf

It is difficult to predict what the costs associated with other future CAR-T therapies will be – there will likely be new or different side effects or additional agents that are co-administered with the therapy that may increase toxicity. The Society urges CMS to take these issues into account as the agency updates the new proposed MS-DRG over time.

Payment for Clinical Trial Cases

CMS is proposing to use an adjustment formula when paying for CAR-T clinical trial cases – proposing that these cases will be weighted at 15% of the weight of the proposed new MS-DRG 018. ASH is supportive of this proposal but urges the agency to provide some flexibility for clinical trial cases involving CAR-T therapy used in conjunction with another treatment. ASH understands and agrees that trials involving novel CAR-T therapies when the treatment is provided at no cost, should not be reimbursed at the standard MS-DRG 018 rate. In other trials, however, the standard of care includes providing CAR-T, but the therapeutic under investigation is something added or ancillary; for examples, ibrutinib added to Kymriah, when the facility must pay for the CAR-T therapy. As currently proposed, this trial would be covered at a fraction of the cost of standard of care therapy – this would disincentivize clinical trials. ASH urges CMS to allow such cases to be included under MS- DRG 018. The cases can be identified with the use of Value Code 90 (previously 86), as the Society requested previously. Value code 90 will allow CMS to see actual acquisition cost for the current CAR-T products.

Proposed Changes to Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

ASH was supportive of the Patients Access to Cellular Therapy Act, which was signed into law in December 2019 as part of (Section 108) the Further Consolidations Appropriations Act of 2020, and is pleased to see this issue addressed in this year's proposed IPPS rule. ASH, joins other medical societies, including the ASTCT and the National Marrow Donor Program (NMDP), with the following concern.

If this proposal is finalized as written, hospitals would no longer be able to report their actual charges; instead, they would be forced to report an average acquisition charge for all patients, regardless of payer. This could have a significant impact on how transplant centers bill commercial insurances for donor search and cell acquisition services. ASH does not believe that CMS intended for this to be the case and urges the agency to abandon its proposal and instead allow transplant centers to continue reporting their actual charges, which will still fully facilitate implementation of Section 108 of the law in the manner Congress intended.

Thank you for the opportunity to provide comments on the proposed rule for the Hospital Inpatient Prospective Payment Systems for 2021. The Society welcomes the opportunity to discuss these comments with you and your team at any time. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager, at lbrady@hematology.org or 716-361-2764 (cell).

Sincerely,

Stephanie J. Lee, MD, MPH
President