

May 5, 2020

American Society for Transplantation and Cellular Therapy 330 N. Wabash Avenue Suite 2000 Chicago, Illinois, 60611

To: Ms. Pickett, Ms. Bullock, and Ms. Hue National Center for Health Statistics ICD-10 Coordination and Maintenance Committee

Via email: nchsicd10cm@cdc.gov, wrp8@cdc.gov, dfp4@cdc.gov and Marilu.Hue@cms.hhs.gov

Re: ICD-10-CM codes for Chimeric Antigen Receptor T (CAR-T) Cell Therapy Associated Immune Effector Cell Associated Neurotoxicity Syndrome for FY 2021 and Personal History of CAR-T

Dear Ms. Pickett, Ms. Bullock, and Ms. Hue:

The American Society for Transplantation and Cellular Therapy (ASTCT) is a professional membership association of more than 2,200 physicians, scientists, and other healthcare professionals who promote blood and marrow transplantation and cellular therapy through research, scholarly publication, and clinical standards. We are dedicated to improving the application and success of hematopoietic cell transplants (HCT) and cellular therapies such as Chimeric Antigen Receptor T-Cell (CAR-T) therapy.

Our membership of hematologists and blood and marrow transplant physicians administer these therapies and manage the associated complications. Ensuring that appropriate diagnosis codes are available to accurately capture CAR-T cell therapy related complications is important to us, which is why we support the finalization of new Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) complication codes and a status code for a personal history of CAR-T by the National Center for Health Statistics (NCHS). The proposal put forth for ICANS was consistent with the ASTCT Consensus Grading Workgroup's Complications Grading Scale paper's description of the various grades of ICANS.¹

The ASTCT supports the proposed tabular modifications to add five grades of ICANS along with a code for unspecified ICANS. ICANS involves the central nervous system, and its symptoms can be progressive, and may include cognitive impairment, motor weakness, and seizures, among others.² Since symptoms are progressive and there are interventions associated with the different grades of ICANS, knowing the specific grade is critical in providing overall patient care.

Establishing individual codes for the different grades of ICANS that can arise in CAR-T patients will enable clinicians and hospitals to more accurately report the level of the complication. This, in turn, will enable comparisons across patients and facilitate analysis of treatment options, length of stay, resource utilization, and outcomes over time.

² Ibid.

 $^{^1}$ ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells, Lee, Daniel W. et al. Biology of Blood and Marrow Transplantation, Volume 25, Issue 4, 625 – 638.



The ASTCT also supports the proposal to create status post cellular therapy codes within Chapter 21 of the ICD-10-CM code set. These codes would enable stakeholders to track CAR-T therapy patients who are subsequently seen in the outpatient setting. Complications and effects of this novel therapy may present weeks, months, or even years later; therefore, it is important to track CAR-T patients over time not only for their continued management, but also to gain a better understanding of the long-term outcomes of the therapy, given that there are still unknowns. It is also possible that this therapy could impact how patients respond to treatments for other, unrelated conditions; hence, it is critical to be able to appropriately identify CAR-T patients who receive care, over time, in the outpatient setting.

For the reasons presented above, the ASTCT supports the finalization of ICANS complication codes and a status code for a personal history of CAR-T. The knowledge gathered during the early years of this new and innovative treatment is fundamental to understanding its impact and outcomes. These include complications, treatments to resolve complications, patient outcomes, and strategies to improve patient outcomes. The information gained from the new codes will be invaluable to clinicians treating patients, the broader field, researchers pioneering new therapies, analysts, payers, and other stakeholders. The ASTCT urges the NCHS to release these new codes as soon as possible.

The ASTCT thanks the NCHS for the opportunity to present these comments and if you have questions, please contact:

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Sincerely,

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