



American Society for
Transplantation and Cellular Therapy

October 26, 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: Bullock, Cheryl (CDC/OPHSS/NCHS) wrp8@cdc.gov; Pickett, Donna
(CDC/OPHSS/NCHS) dfp4@cdc.gov

Re: ICD-10-CM Code Change Requests for a Complication of Immune Effector Cellular (IEC) Therapy, Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS), and Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy

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 HCT and CAR-T cell therapy related complications is important to us for both clinical and research purposes.

For this reason, the ASTCT supports the requests for coding changes in order to better capture complications of CAR-T therapy. Specifically, we urge CMS to:

1. implement a new code under T80 to capture a complication of immune effector cell therapy,
2. finalize new Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) complication codes. The ICANS proposal is consistent with the ASTCT Consensus Grading Workgroup's Complications Grading Scale's description of the various grades of ICANS,¹ and
3. implement a new code to identify hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). As with complications of CAR-T therapy,

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.



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the ASTCT believes that it is important to be able to code for the *specific* diagnoses of complications that follow HCT.

Our rationale is presented below.

1. Code Request for Complication of Immune Effector Cellular (IEC) Therapy

The ASTCT fully supports the Alliance of Dedicated Cancer Centers' (ADCC) request for a single new code to capture complications of Immune Effector Cell (IEC) therapy. The ADCC's request would involve the creation of a new code, T80.82 (Complication of immune effector cellular therapy), and the addition of a "use additional code" note to identify the specific complication, including cytokine release syndrome (D89.83-) and immune effector cell-associated neurotoxicity syndrome (G92.0). Our member physicians are already evaluating patients and capturing the occurrence of complications of IEC therapy in their documentation, therefore the implementation of this code will enable a higher degree of specificity in the coded data and advance efforts to track the critical complications of IEC therapy.

2. Finalization of New Codes for Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS)

The ASTCT was pleased that the National Center for Health Statistics (NCHS) finalized codes for the different grades of cytokine release syndrome (CRS), that were implemented October 1, 2020. We had initially hoped that the ICANS codes would have been finalized for use this October as well, but recognize that the NCHS required more time to review them. We were pleased that, at the September 2020 meeting, the NCHS discussed the need for ICANS codes that are also differentiated by the various grades of CRS.

The ASTCT supports the proposed tabular modifications to add five grades of ICANS along with a code for unspecified ICANS. This proposal reflects the consensus achieved in the cellular therapy community on how to evaluate, grade, and document ICANS. ICANS involves the central nervous system; 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, it is critical to know the specific grade in order to provide 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.

The ASTCT urges the NCHS to finalize the creation of a new T code (T80.82) to capture complications of IEC therapy, along with releasing new codes for ICANS as soon as

² 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.



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possible. These codes, along with the previously created cytokine release syndrome codes, will ensure that the most common complications of immune effector cell therapy can be appropriately coded and tracked.

3. Code Request for Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy

Like other stakeholder organizations, ASTCT members track the various complications associated with stem cell transplantation. The work to track, monitor, and evaluate complications after transplants is particularly important for severe complications, such as transplant-associated thrombotic microangiopathy (TMA).

Currently, the ICD-10-CM coding set does not differentiate between HSCT-TMA and other types of TMA, however. The existing code, M31.10, is for TMA. Yet, HSCT-TMA is a *specific* complication occurring after HCT—it is caused by the procedure itself and has unique comorbidities that differentiate it from other types of TMA. The lack of a separate code impedes the work of tracking and research to improve clinical outcomes.

Therefore, the ASTCT supports the proposed tabular modifications. We welcome the addition of a new code to identify this complication of HCT, M31.11, Hematopoietic stem cell transplantation-associated thrombotic microangiopathy (HSCT-TMA).

Summary

The field of hematopoietic transplantation and cellular therapy continues to advance, as does the need to identify specific diagnoses of complications of transplant and cellular therapy. The information gained from the proposed new codes will be invaluable to clinicians treating patients, the broader field, researchers pioneering new therapies, analysts, payers, and other stakeholders.

The ASTCT thanks the NCHS for the opportunity to present these comments and if you have questions, please contact: Alycia Maloney, Director of Government Relations for the ASTCT at (202) 367-1254 or amaloney@astct.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Pavan Reddy".

Pavan Reddy, MD
Frances and Victor Ginsberg Professor of Hematology/Oncology
Chief, Division of Hematology/Oncology
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