ASTCT
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
Centers for Medicare and Medicaid Services
ICD-10 Coordination and Maintenance Committee
Via email: Hue, Marilu (CMS/CM) Marilu.Hue@cms.hhs.gov

Re: ICD-10-PCS Code Change Requests for the Administration of CAR-T Immunotherapies, for Allogeneic CAR-T Administration, and Two New Therapies

Dear Ms. Hue:

The ASTCT is a professional membership association of more than 2,200 physicians, scientists, and other healthcare professionals that 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 other cellular therapies. Our membership of hematologists and blood and marrow transplant physicians are the expert providers who typically administer these therapies; the ability to reflect this work via the ICD-10-PCS coding system is important to us from a clinical, research, and reimbursement perspective.

Our comments below focus on three topics from the September 8, 2020 ICD-10 Coordination and Maintenance Committee Meeting, all related to Chimeric Antigen Receptor T-cell (CAR-T) therapy or cellular therapies:

(1) coding for the administration of autologous CAR-T therapy using the existing coding table or by moving codes to a new table,
(2) administration of allogeneic CAR-T therapy, and
(3) code requests for the administration of two new therapies: lifileucel, and idecabtagene vicleucel.

1. Coding for Chimeric Antigen Receptor T-cell Immunotherapies and Engineered Cell Therapies

The ASTCT was pleased that the September 2020 meeting agenda included the topic of how CAR-T and other cellular therapies should be structured under ICD-10-PCS. In May, CMS assigned the codes for two new CAR-T products to a new Section X ICD-10-PCS table, XW2, while leaving the existing products in the XW0 table. Stakeholders, including the ASTCT, felt that the XW2 – a transfusion table – was inappropriate for the

coding of CAR-T and other FDA approved cellular therapies. We are grateful that CMS heard stakeholders' concerns about this issue and engaged in a discussion where the following options were presented for how to handle the coding of existing and new CAR-T therapies as well as other cellular therapies:

- Option 1: status quo (make no changes).

- Option 2: add product-specific ICD-10-PCS codes for the administration of each specific CAR-T product (and in the case of lifileucel, a TIL product) to the XW2, and move the non-product specific codes for the existing two therapies to the XW2 table.

- Option 3: move the newly assigned ICD-10-PCS codes from the XW2 table into the XW0, and replace existing non-product-specific CAR-T codes in the XW0 table for tisagenlecleucel and axicabtagene Ciloleucel with product-specific ICD-10-PCS codes.

The ASTCT has reviewed these options and supports option 3 not only for existing CAR-T product codes, but also for lifileucel and Lisocabtagene maraleucel.

CAR-T products are modified using a patient's own T-cells (or, for up-and-coming allogeneic therapies, a donor's T-cells), and these cells are collected from blood. Nonetheless, we do not believe any stakeholder in this field would consider CAR-T products to be "blood or blood products," as described in the root operation of table XW2. Rather, CAR-T immunotherapies are genetically modified products.

The Chimeric Antigen Receptor (CAR) is a special receptor that is created in a laboratory and is added to the individual's T-cells. The CAR is, therefore, man-made, and the resulting T-cells are fundamentally altered by its addition to them. For this reason, we consider CAR-T immunotherapies to be a *therapeutic substance*, not a blood product. Hence, CAR-T immunotherapies and other cellular therapies align more appropriately with the root operation of the XW0 table rather than XW2.

Option 3 also preserves the non-product-specific autologous CAR-T administration codes, enabling their continued use for research and development of future autologous CAR-T therapies and keeps them separate from FDA-approved products. This option allows full visibility into each specific FDA product administered to inpatients, which is critical for clinical analysis and research on safety and effectiveness.

The ASTCT believes that, under Option 3, no codes would remain in the XW2 table; hence, we recommend that CMS eliminate this table.

We urge CMS to finalize Option 3 for each of the above agenda items as soon as possible, however we recognize that CMS' normal cycle would have these changes going into effect in FY 2022. While we understand this, we are concerned that coding professionals may be confused in FY 2021, given there are two different ways to code FDA approved cellular therapy products. In

coding, consistency is critical, as is having visibility of each FDA product that is administered in the inpatient setting. Therefore if it is at all possible, we encourage CMS to implement Option 3 sooner, particularly if there is consensus on this request across stakeholders.

2. Code Request for the Administration of Allogeneic CAR-T-Cell Immunotherapy

The ASTCT thanks CMS for the opportunity to present this request for a code to describe the administration of allogeneic CAR-T therapy at the September 2020 meeting. As we noted in our presentation, creation of an allogeneic non-product specific CAR-T code is important. It is needed in order to maintain the non-product specific autologous codes in the XW0 table, as described above in Option 3 for CAR-T immunotherapies.

Ongoing clinical research and development of allogeneic CAR-T products necessitates having separate codes in the XW0 table. It is inappropriate and confusing for coding professionals to continue to report these therapies with different ICD-10-PCS codes from the 3E0 administration table—including reporting them as anti-neoplastics or other therapeutic substances. Of the three options advanced at the September public meeting, the ASTCT support Option 3, for the same reasons cited above. This option involves creating new XW0 non-product-specific codes to report non-FDA approved allogeneic products.

Finalizing Option 3 will allow for consistency across all CAR-T administration codes within the root operation of the XW0, which indicates introduction of a therapeutic substance. Finally, the addition of the allogeneic engineered CAR-T-cell immunotherapy code will be an appropriate compliment to the existing autologous administration codes.

3. Section X Updates

The ASTCT was pleased that CMS raised the question of the long-term use of Section X codes at the September 2020 public meeting. We appreciate CMS' responsive to stakeholder questions about the agency's plans for managing Section X codes over time. CMS shared that it is looking at either migrating codes out of Section X and into an existing ICD-10-PCS coding table or eliminating the codes altogether if the service can be described through an existing code. The ASTCT is very interested in this discussion, the evolution in coding policy, and the application to XW0 codes for CAR-T and other cellular therapy products.

As CMS moves forward with changes to the Section X tables, we urge the agency to continue to track and give visibility to *all* engineered cellular therapies. CMS can do so either by leaving these therapies in the XW0 table or move them to another table but continue to require their specific names be a part of the ICD-10-PCS code or work with CMS to have the national drug code (NDC) be reported on claims. We will continue to evaluate this issue and look forward to discussions with CMS on these issues.

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Summary

In summary, the ASTCT supports granularity and consistency in the ICD-10-PCS coding in general, and, specifically as this relates to CAR-T therapy and other cellular therapies.

We believe it is important to identify FDA-approved CAR-T products specifically, by name, when they are administered in the inpatient setting. We also believe it is also crucial to identify the administration of non-FDA approved CAR-T products through the use of generic ICD-10-PCS codes in the XW0 table. This will enable all products to be consistently coded using a single table, the XW0 table.

If you have any questions, or wish to discuss other options, please do not hesitate to contact Alycia Maloney, ASTCT's Director of Government Relations, at (202) 367-1254 or amaloney@astct.org.

Sincerely,

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