VIA ELECTRONIC DELIVERY

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To: nchsicd10CM@cdc.gov
Centers for Medicare & Medicaid Services
CMS ICD-10-PCS Coordination and Maintenance Committee

Subject: Support of Option 3 for Coding Chimeric Antigen Receptor T-cell Immunotherapies.

The Alliance for Regenerative Medicine (ARM) and the Biotechnology Innovation Organization (BIO) appreciate this opportunity to submit comments on the proposed new codes and revisions discussed at the September 8-9, 2020 ICD-10 Coordination and Maintenance Committee Meeting.

ARM is the leading international advocacy organization dedicated to realizing the promise of regenerative medicines and advanced therapies. ARM promotes legislative, regulatory and reimbursement initiatives to advance this innovative and transformative sector, which includes cell therapies, gene therapies and tissue-based therapies. Early products to market have demonstrated profound, durable and potentially curative benefits that are already helping thousands of patients worldwide, many of whom have no other viable treatment options. Hundreds of additional product candidates contribute to a robust pipeline of potentially life-changing regenerative medicines and advanced therapies. In its 11-year history, ARM has become the voice of the sector, representing the interests of 370+ members worldwide, including small and large companies, academic research institutions, major medical centers and patient groups.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

The regenerative medicine and advanced therapies sector is the next frontier in the fight against some of humankind's most devastating diseases and disorders. As of mid-2020, ARM estimates there are 1,001 regenerative medicine and advanced therapies developers worldwide sponsoring 1,078 clinical trials across dozens of indications, including oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.[1]

[1] https://alliancerm.org/sector-report/h1-2020-report/

I. Background

Effective October 1, 2020, ICD-10-PCD codes for the intravenous administration of CAR T-cell therapies can be identified in two different tables in the classification system. In addition, two existing ICD-10-PCS codes for the intravenous administration of CAR T-cell therapies are not product specific, while two of the codes that were effective October 1, 2020 are product specific. Specifically, here are the current coding options as of October 1, 2017.

Facilities can report the intravenous administration of CAR T-cell therapies with one of the following ICD-10-PCS codes from table XW0:

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**C** Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy	**3** New Technology Group 3

Effective October 1, 2020, facilities can report the intravenous administration of Tecartus™ (brexucabtagene autoleucel) or lisocabtagene maraleucel with one of the following ICD-10-PCS codes from table XW2:

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**2** Transfusion: Putting in blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**4** Brexucabtagene Autoleucel Immunotherapy **7** Lisocabtagene maraleucel Immunotherapy	**6** New Technology Group 6

Given these coding inconsistencies for the same technology, CMS presented three different options for public comment to resolve these issues. During the September meeting, CMS also reviewed options for the procedure code application to recognize the Administration of Lifileucel. It is appropriate to review these coding options together as they represent available and soon-to-market cell therapies and the coding construct should be consistent across therapies.

II. Proposal for Chimeric Antigen Receptor T-cell Immunotherapies

During the September meeting, the following three coding options were presented:

Option 1. Do not create new ICD-10-PCS codes. Continue using codes as listed in current coding.

Option 2. Create new codes in section X, New Technology, in table XW2 Transfusion to identify intravenous transfusion of CAR T-cell products KYMRIAH® (tisagenlecleucel) and Yescarta® (axicabtagene ciloleucel). Also add non-product specific codes in table XW2 to identify the transfusion of other engineered autologous CAR T-cell therapies. Delete codes in table XW0 that identify the intravenous infusion of CAR T-cell therapies.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**2** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**4** Brexucabtagene Autoleucel Immunotherapy **7** Lisocabtagene Maraleucel Immunotherapy	**6** New Technology Group 6
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD F** Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Autologous **ADD H** Axicabtagene ciloleucel Immunotherapy **ADD J** Tisagenlecleucel Immunotherapy	**ADD 7** New Technology Group 7

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**A** Bezlotoxumab Monoclonal Antibody **B** Cytarabine and Daunorubicin Liposome Antineoplastic **DELETE C** Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy **F** Other New Technology Therapeutic Substance	**3** New Technology Group 3

Option 3. Create new codes in section X, New Technology, in table XW0 Introduction to specifically identify intravenous infusion of CAR-T products KYMRIAH® (tisagenlecleucel), Yescarta® (axicabtagene ciloleucel), Tecartus™ (brexucabtagene autoleucel) and lisocabtagene maraleucel. Revise the device value C to "Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Autologous" to identify the infusion of other engineered autologous CAR-T cell therapies. Delete table XW2 that identifies the intravenous transfusion of Tecartus™ (brexucabtagene autoleucel) or lisocabtagene maraleucel.

Section *Body System* *Operation*	**X** New Technology **W** Anatomical Regions **0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**REVISE FROM C** Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy **REVISE TO C** Engineered Chimeric Antigen Receptor T-cell Immunotherapy, Autologous	**3** New Technology Group 3
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD H** Axicabtagene ciloleucel Immunotherapy **ADD J** Tisagenlecleucel Immunotherapy **ADD M** Brexucabtagene Autoleucel Immunotherapy **ADD N** Lisocabtagene maraleucel Immunotherapy	**ADD 7** New Technology Group 7

Section *Body System* *Operation*	**X** New Technology **W** Anatomical Regions **DELETE 2** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**DELETE 4** Brexucabtagene Autoleucel Immunotherapy **DELETE 7** Lisocabtagene Maraleucel Immunotherapy	**6** New Technology Group 6

III. Consistent with Public Comments, ARM and BIO Support Option 3 for Administration of CAR T-cell Therapies

ARM and BIO are concerned that two of the CAR T therapies are being described as a blood or blood product when each of the products clearly meets the FDA definition of biologic, is regulated by the FDA as such, and clearly meets the Operation description of the table entitled, "Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products."

We appreciate that CAR T therapies are derived from the patient's blood and therefore when administered to the beneficiary could be described as a transfusion of a blood product, but this literal approach of the CAR T administration will likely cause confusion given the CAR T's significant therapeutic benefit as compared to a simple transfusion of a blood or blood product. Each substance behaves very differently in the patient and we urge CMS to finalize Option 3.

IV. <u>ARM and BIO support Option 3 for Administration of Lifileucel</u>

We support Option 3 to recognize the Administration of Lifileucel, an autologous Tumor Infiltrating Lymphocyte (TIL) cell-based therapy being studied for effectiveness in solid tumors. Both TIL and FDA approved CAR T-cell therapies are autologous, start with the collection of a patient's cells and then are re-administered to the patient. Similar to CAR T, for the TIL therapy with lifileucel, the T-cells are directly isolated from resected tumor tissue and expanded ex vivo.

Following a complex manufacturing process, the patient is intravenously infused with the lifileucel, where the TIL migrates back into the tumor, triggering specific tumor cell killing upon recognition of tumor antigens.

Consistent with the CAR-T proposal, CMS proposed three coding options. In order to ensure consistency across cell therapies, ARM and BIO support Option 3, which would create new codes in section X New Technology, table XW0 Introduction, to identify intravenous administration of lifileucel, as described below.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD L** Lifileucel Immunotherapy	**ADD 7** New Technology Group 7

V. CMS should update the definition of 0 Introduction to recognize cell therapies

To ensure clarity and future consistency, ARM and BIO recommend that CMS update the definition of "0 Introduction". Specifically, the table element is currently defined as "0 Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products". CMS should update this definition to read "*0 Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, prophylactic substance or cell therapy including blood-derived products and other cellular technologies.*"

VI. Conclusion

We believe that is critical for CMS to develop and implement policies and programs that support the appropriate use and identification of new technologies. The need for unique, product-specific ICD-10-PCS code for each CAR T therapy is further underscored by their utility in helping facilitate NTAP payments, where those therapies are eligible for NTAP. Further, it is important for CMS to implement these coding changes as soon as possible in order to ensure that the implementation of the new MS DRG 018 enables patient access to these CAR T therapies as soon as possible.

We thank CMS for its proposals and look forward to working with CMS to establish coding policies that promote appropriate access to and identification of new and innovative therapies in both the near term and long.

Sincerely,

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