



American Society for
Transplantation and Cellular Therapy

April 8, 2022

Ms. Marilue Hue
Centers for Medicare & Medicaid Services (CMS)
ICD-10 Coordination and Maintenance Committee

SUBMITTED ELECTRONICALLY VIA Marilu.Hue@cms.hhs.gov, ICDProcedureCodeRequest@cms.hhs.gov

RE: ICD-10-PCS code requests discussed at the March 8, 2022 meeting

Dear Ms. Hue and CMS staff:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased submit our comments on ICD-10-PCS code change requests discussed at the March 8, 2022 ICD-10 Coordination and Maintenance Committee public meeting.

The ASTCT is a professional membership association of more than 3,000 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. The clinical teams within our society have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including chimeric antigen receptor T-cell (CAR-T) therapy.

The members of ASTCT have been focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases, for more than 25 years. Being able to accurately reflect the procedures involved in the delivery of these therapies, including cell and gene therapy, through the ICD-10-PCS coding system is important to the ASTCT.

We submit our comments on three topics: ASTCT support for the placement of new code requests to describe the administration of therapies that are seeking New Technology Add-On Payment (NTAP), the code change request relating to *ex vivo* autologous hematopoietic stem cell gene therapies, and the recent ICD-10 C&M meeting processes.

The ASTCT supports CMS’ indicated placement for certain NTAP-related code requests.

Four cell and gene therapies may be seeking NTAP for the FY 2023 or FY 2024 cycles and thus were not publicly discussed at the March 8th meeting. ASTCT supports CMS’ proposed placement of these therapies, as summarized below.

Therapy Name	Therapy Type*	CMS Placement
Afamitresgene autoleucel	Autologous adoptive cell transfer therapy	Option 2 (Table XW0)
Betibeglogene autotemcel	Autologous hematopoietic stem cell gene therapy	Option 2 (Table XW1)
Omidubicel	Allogeneic hematopoietic stem cell-based cellular therapy	Option 2 (Table XW1)
Tabelecleucel	Allogeneic virus-specific T-cell immunotherapy	Option 2 (Table XW0)

**As described in each applicant’s materials*

ASTCT feels that new technologies that are comprised of modified hematopoietic stem cells and that will be utilized in the process of stem cell transplantation episodes of care are in alignment with the Root Operation *Transfusion: Putting in blood or blood products*, and thus should be placed in the XW1 table, as CMS has indicated. ASTCT also concurs with CMS on the placement of the two cellular immunotherapies with Root Operation *Administration: Introduction of a substance other than blood and blood products*.

The ASTCT supports Option 2 (Table XW1) for Topic #11 - Ex Vivo Autologous Hematopoietic Stem Cell Gene Therapy.

We are grateful to CMS for listening to comments from ASTCT and other stakeholders during the September 2021 meeting on the assignment of genetically modified hematopoietic stem cell gene therapies into the 302 Table and for bringing this topic back as topic #11 on the agenda for public discussion in March 2022. The changes put forward in the Addenda topic at the September 2021 meeting gave the ASTCT and others concern about consistency in the coding table and the inclusion of diagnoses within the substance description of the codes.

The ASTCT supports CMS’ proposed option 2, placement in the XW1 table, for topic #11. We also support the specific naming of products in the Section X tables in general – versus using a “generic” term - as it is important to be able to identify which novel therapies are given to patients and to track outcomes over time. In parallel, we support the inclusion of generic codes in Section X tables, as those codes can be used to identify new types of therapies or procedures under clinical trial before FDA approval and/or before new code availability.

The Cellular Therapy Committee of the ASTCT is currently drafting a paper that defines the various subtypes of cell and gene therapies. We will circulate this publication to CMS in the second half of 2022 for your reference and would welcome the opportunity to have a discussion with the agency, as it will be important to understand and group different subtypes of therapies as they are approved.

There are numerous terms currently in circulation to describe these novel therapies, some for good reason based on audience type, but there are differences and distinctions that can be made for purposes of finalizing these and future coding requests.

Prior to publication of this resource, the ASTCT offers the following comments to help CMS understand our perspectives on how the products currently under discussion may be differentiated from one another and mapped to appropriate coding tables.

- Hematopoietic stem cells (HSCs) are immature cells found in the blood marrow, cord blood and peripheral blood that can develop into all types of blood cells, including white blood cells, red blood cells and platelets.¹ Stated another way, HSCs are the precursor cells that give rise to almost everything that fits within the term “blood and blood products.” These cells are currently identified in the Substance Character in Table 302 as: Y (Stem Cells, Hematopoietic), C (Hematopoietic Stem/Progenitor Cells, Genetically Modified), X (Stem Cells, Cord Blood) and U (Stem Cells, T-cell Depleted Hematopoietic).
- The products associated with request topic #11 are gene therapies, as they are indicated to correct a genetic disorder. However, they are a subtype of gene therapy - an *ex vivo* hematopoietic stem cell gene therapy – that is delivered via a hematopoietic stem cell transplant episode of care. We consider these *ex vivo* HSC gene therapies to be an evolution in hematopoietic stem cell transplant, not unlike how drug eluting stents were an evolution of regular stenting for cardiac procedures.
- The formulation and administration of the current *ex vivo* HSC gene therapies involves autologous cell mobilization and collection, the administration of a myeloablative conditioning regimen, and the transfusion of the *ex vivo* modified hematopoietic stem cells to the patient in order to restore hematopoietic function and correct the pathologic issue being driven by the genetic anomaly. This process is almost identical to non-genetically modified stem cell transplants, which are coded out of the 302 Table.
- These HSC transplant episodes of care – whether the transplanted material is genetically modified or not - are differentiated in their clinical purpose and process from other cellular immunotherapies, such as CAR-T, in that the restoration of the patient’s hematopoietic/immune function is dependent upon the infusion of the stem cell product after myeloablation. If a CAR-T product was not administered as planned after the patient preparation process, the patient’s hematopoietic system would be intact, though still diseased.
- The commonality between the procedures and products represented by tables 302 and those proposed for placement in XW1 is that both are comprised of cell types that support or restore one or more aspects of hematopoietic functionality. This is different from those therapies that may utilize a specific type of immune effector cell for antineoplastic purposes – such as CAR-T – which are more appropriate in their current placement within XW0.

¹ National Cancer Institute Dictionary: [Hematopoietic Stem Cell](#). Accessed April 4, 2022.

Those HSC transplant episodes of care not utilizing a new technology HSC product are currently coded from the 302 table, with *Transfusion* as the root operation. Therefore, finalizing Option 2 for topic #11 (placement in the XW1 table) seems the most appropriate choice for the placement of two new *ex-vivo* HSC gene therapies as it allows the same root operation (Transfusion) to be used. Selecting Option 2 will also enable CMS to create consistency with its own recommendations for the other hematopoietic stem cell therapies seeking new codes, for which CMS recommended placement in XW1 (see previous NTAP summary table on page 3).

During the meeting, a commenter stated that they preferred CMS' Option 3 for topic #11, which entailed placement of the therapies into the XW0 table due to the fact that Transfusion as a root operation "typically" reflects whole blood or non-modified blood derivatives, such as plasma. The ASTCT agrees that the commenter's statement is in historical and factual alignment with the types of procedures and products reflected in the current 302 table. However, the XW1 table is the *New Technology* version of the 302 table and therefore – by design – will include blood and blood products that have been modified (genetically or otherwise) and are not otherwise accurately described by the options within 302. If CMS is not in agreement with our understanding of the intent of Table XW1, we ask for future clarification of the table's purpose.

One of CMS' proposed options (#4) was to revise current Substance C in Table 302 from "Hematopoietic Stem/Progenitor Cells, Genetically Modified" to "Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo." The ASTCT is not advocating for this option as we feel that specific product visibility in the data benefits all stakeholders. However, we would ask that CMS consider movement of this code to the XW1 table alongside the product-specific codes, to be consistent with its precedent of the placement of both specific and generic therapy descriptor codes together in the New Technology tables, such as it has for CAR-T. The ASTCT is supportive of the proposed addition of the "Ex Vivo" terminology – while not absolutely necessary, it adds a level of clarity that could be useful to coding professionals.

Last, we ask that CMS consider modification of the Substance names in the topic #11 request, from OTL-103 and OTL-200 to either the full scientific name or the trade name of the products, so as to be consistent with the other nomenclature utilized in the New Technology tables and to reflect the terminology that will be utilized in the physician notes utilized by coding professionals. As the representative of Orchard Therapeutics noted on the call, both products have different names available (e.g. OTL-200 = Libmeldy) and we encourage CMS to work with the requestor to utilize a Substance name that is more recognizable by coding professionals.

The ASTCT values the opportunity to participate in the ICD-10 C&M meetings and wants to ensure that our members can participate.

While the bulk of our commentary in this letter thus far has been focused on the codes themselves, we offer the following suggestions in relation to the ICD-10 C&M meeting process. **First, we reiterate our request from prior coding cycles to release the meeting materials further in advance, with a minimum of one calendar week.** Posting of the materials less than 48 hours in advance of the meeting is untenable for physician-based organizations to be able to thoughtfully participate in the discussion related to the meeting, either as part of a preparatory review discussion or in real-time.



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Our ASTCT members are practicing clinicians and while very interested in the ICD-10 C&M meeting content – and likely to have meaningful contributions - they are unable to review and discuss the materials within the appropriate committee structures given this short timeframe.

Second, given the interest in these topics from multiple stakeholders, we ask that CMS consider allotting additional discussion time for the code change topics that are associated with cell and gene therapy procedures. Given the involved discussion about the procedure codes for gene therapies that took place at the September 2021 meeting, ASTCT had asked physicians representing our Cellular Therapy Committee to participate in the March 8th discussion. These physician representatives modified their clinic schedules to be present on the line. When called upon, CMS was unable to unmute the physician’s line successfully and moved to another commenter, but then only allowed that one commenter to speak before moving to another topic in order to stay on track for the mid-day break. While we are sympathetic to the technological challenges associated with a virtual meeting, and the interest in staying aligned with the agenda, our physician representatives were anticipating a far more robust discussion to take place on Topic #11 since it was essentially an unresolved item from the September 2021 meeting. We expect that some of the issues that we wanted to raise during this discussion will surface again in future ICD-10 C&M meetings because there will continue to be underlying challenges regarding the appropriate definitions – and therefore the coding of these types of therapies.

Additionally, we expect cell and gene therapies seeking new ICD-10-PCS codes to continue being split between two coding procedural tracks – 1) those seeking NTAP, and therefore not open to public discussion and 2) those not seeking NTAP, subject to a public discussion – due to natural differences in patient populations and payer mix. Regardless of NTAP status, these coding requests are all associated with a new area of medicine that needs thoughtful consideration as it is written into the coding frameworks. Our overarching concern is that coding decisions that apply to cell and gene therapies could be made inconsistently between these categories, if there is not an opportunity to have a broader discussion about categories of therapies and/or requests.

We are not requesting that CMS pull these NTAP items back into the public discussion portion of the meeting, but we are asking that sufficient time for discourse be allocated to similar items that are on the discussion agenda, or that a time for open dialogue on the recommendations made for those products that may be seeking NTAP be allotted, particularly given the history of the topic at the last meeting. Four of the thirteen NTAP applicants code change requests posted by CMS prior to the meeting are related to cell and gene therapies, but with no specific opportunity to discuss them during the meeting, the common issues could only be raised during topic #11, and only somewhat indirectly. While we are submitting comments after the meeting, as CMS directed, these comments are not made publicly accessible and are not a substitute for synchronous dialogue between stakeholders in the coding community so that all participants may benefit. **We repeat our request from our September 2021 letter that CMS plan for a discussion of how to appropriately structure and place codes for cell and gene therapies, as multiple therapies of this type are expected to seek FDA approval in each upcoming year.**



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The ASTCT wishes to express its appreciation for the CMS staff leading these coding meetings and the opportunity to provide these comments. We welcome the opportunity to discuss these recommendations in more detail or to answer any questions you may have. Please contact Alycia Maloney, ASTCT Director of Government Relations, at amaloney@astct.org for any follow-up issues.

Sincerely,

A handwritten signature in blue ink, appearing to read "S. Davies".

Stella M Davies, MBBS, PhD, MRCP
President, ASTCT