



American Society for  
Transplantation and Cellular Therapy

September 13, 2022

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

*Submitted electronically at regulations.gov*

**Re: CMS-1772-P: CY 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating**

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the Calendar Year (CY) 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule.

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 in our society continue to develop and implement clinical care standards which advance the science of cellular therapy, including participation in trials that lead to current FDA approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases. ASTCT members are involved in the infusion of CAR-T therapies and cell therapies to treat blood cancers, and for solid tumors, due to the specialized expertise required to safely administer these products in the clinical setting. Additionally, ASTCT members are at the forefront of clinical trials examining the use of *ex vivo* genetically edited hematopoietic stem cells delivered via a stem cell transplant, for treatment of genetic blood disorders, including beta thalassemia and sickle cell disease, along with immune deficiency and metabolic disorders.

The approvals—or anticipated approvals—of novel cellular immunotherapies and gene therapies have highlighted challenges within the Medicare coverage, coding, and payment systems. The ASTCT remains concerned about the potential barriers to care these challenges may cause. We are committed to working with CMS to find solutions that ensure patient access to these therapies without creating financial harm to the clinicians providing them.



American Society for  
Transplantation and Cellular Therapy

To that end, the ASTCT wishes to comment on several aspects of the CY 2023 OPPS proposed rule, given their implications for cell and gene therapies and stem cell transplantation:

- We request that CMS does not finalize its proposal to change the status indicator (SI) for axicabtagene autoleucel (HCPCS product Q2041) to “N”, and instead maintains the current status indicator of “K”;
- We request that CMS map cell therapy and gene therapy-affiliated revenue codes to specific cost centers rather than labeling them as “reserved” in the outpatient cost center crosswalk file; and
- We request that CMS consider implementing an annual cap on individual APC payment rate fluctuation for OPPS Ambulatory Payment Classifications (APCs).

The ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions that CMS may have. Please contact Alycia Maloney, ASTCT’s Director of Government Relations at [amaloney@astct.org](mailto:amaloney@astct.org) for any follow up issues.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Sandmaier". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Brenda M. Sandmaier, M.D.  
President, American Society for Transplantation and Cellular Therapy  
Professor, Fred Hutchinson Cancer Center  
Professor of Medicine, University of Washington



American Society for  
Transplantation and Cellular Therapy

**I. Request to Retain Current Status Indicator for HCPCS Code Q2041**

In Addendum B, released with the CY 2023 OPSS proposed rule, the HCPCS product Q-code for the CAR-T therapy axicabtagene autoleucel (axi-cel; Q2041), was proposed to change from status indicator (SI) “K” to “N”, meaning that it would be packaged into APC rates. The file also included a Comment Indicator (CI) of “CH”, indicating the SI and APC assignment are proposed to change.

We believe CMS may have made an inadvertent technical error when proposing the Addendum B file that resulted in this proposed change in status indicator. We request that the agency address this in the final rule by finalizing the status indicator of “K” for axi-cel for 2023, which is its current status indicator today, rather than “N”. The ASTCT strongly believes it is inappropriate to package HCPCS code Q2041, given that its cost exceeds the drug packaging threshold, and because axi-cel is not a policy-packaged drug. Axi-cel, like all other CAR-T therapies, should remain a separately payable non-passthrough biological, as it is today. Finalizing a SI of “N” for axi-cel would be a significant problem for providers, as it would mean there would be no separate payment for this biological, despite it having a current payment rate of \$422,770.92 under APC 9035 based on the ASP +6%.

*The ASTCT urges CMS to finalize a SI of “K” for Q2041 and retain the code’s current APC assignment and ASP-based payment in the CY 2023 OPSS final rule.*

**II. Request that CMS Reflect NUBC Definitions and Map Revenue Code Series 087x and 089x Under OPSS**

CMS publishes a Revenue Code to Cost Center Crosswalk with each OPSS rule. For the crosswalk published with the CY 2023 OPSS proposed rule, the ASTCT notes that the entire revenue code series for 087x and 089x are marked “RESERVED” in the crosswalk. We have included the full listing of both series in a modified excerpt of CMS’ table below, showing only columns A-C from CMS’ file, along with an additional column we added reflecting NUBC descriptions for CMS’ reference.

2021 Revenue center ID	Description (applicable to CY 2021 claims)	Used in 2023 OPSS (2021 claims)	NUBC Description
0870	RESERVED	N	Cell/Gene Therapy – General Classification
0871	RESERVED	N	Cell Collection
0872	RESERVED	N	Specialized Biologic Processing and Storage - Prior to Transport
0873	RESERVED	N	Storage and Processing after Receipt of Cells from Manufacturer
0874	RESERVED	N	Infusion of Modified Cells
0875	RESERVED	N	Injection of Modified Cells



American Society for  
Transplantation and Cellular Therapy

0876	RESERVED	N	RESERVED
0877	RESERVED	N	RESERVED
0878	RESERVED	N	RESERVED
2021 Revenue center ID	Description (applicable to CY 2021 claims)	Used in 2023 OPPS (2021 claims)	NUBC Description
0879	RESERVED	N	RESERVED
0890	RESERVED	N	RESERVED
0891	RESERVED	N	Special Processed Drugs – FDA Approved Cell Therapy
0892	RESERVED	N	Special Processed Drugs – FDA Approved Gene Therapy
0893	RESERVED	N	RESERVED
0894	RESERVED	N	RESERVED
0895	RESERVED	N	RESERVED
0896	RESERVED	N	RESERVED
0897	RESERVED	N	RESERVED
0898	RESERVED	N	RESERVED
0899	RESERVED	N	RESERVED

The ASTCT is concerned that codes in the 087x and 089x series, which the National Uniform Billing Committee (NUBC) has explicitly defined (i.e., 0870-0874, 0891 and 0892), remain flagged as “RESERVED” by CMS, and are therefore not mapped for OPPS rate setting. We believe the only codes that should remain “RESERVED” in CMS’ Revenue Code to Cost Center Crosswalk are the ones that the NUBC considers reserved, which include 0876-0879, 0890 and 0893-0899. Our understanding is that CMS’ revenue code mapping should be reflective of the current revenue code designations established by the NUBC, due to the NUBC’s role as the designated standards maintenance organization for revenue codes.

***We request that CMS update its OPPS mapping to reflect the NUBC definitions in the CY 2023 Final Rule files, which means that revenue codes 0870-0874, 0891 and 0892 would no longer be shown as “RESERVED”.***

In addition to using the NUBC revenue code definitions, it is critically important that CMS ensure these revenue codes are appropriately mapped to the right cost centers under OPPS. Hospitals completing their cost reports need to be able to match the departmental staff and expense involved in the delivery of these services with the revenue billed for the services. The near-term cell and gene therapy pipeline is robust, and many of these products will either be delivered to hospital outpatients or will have ancillary services performed on hospital outpatients before or after an inpatient administration of the therapy. The ASTCT sees the need for CMS to explain how the costs of these outpatient services are addressed in the inpatient and outpatient prospective payment systems as crucial in light of the anticipated volume increases.

The ASTCT requests that CMS map the revenue codes shown in the table below to cost centers in a manner that accurately reflects the cost centers having the expense of the clinical services being performed. We recommend the following mapping for the NUBC-designated revenue



American Society for  
Transplantation and Cellular Therapy

codes, based on our understanding of the most appropriate cost group to account for the correct departments in the hospital from which the cost for these services originates.

Revenue Code	NUBC Description	Recommended Cost Group	Other Revenue Codes with Similar Expense /Mapping	Description of the Service
0870	Cell/Gene Therapy – General Classification	6000, clinic	0510, 0761, 0940, 0949	General Classification for Cell/Gene therapy services
0871	Cell Collection	6000, clinic	0510, 0761, 0940, 0949	<i>0871 for Cell Collection:</i> Staff who perform apheresis collections are licensed nurses associated with clinics and/or other therapeutic departments of hospitals that furnish apheresis services. Given this, the most appropriate cost group is the 6000.
0872	Specialized Biologic Processing and Storage - Prior to Transport	3350, laboratory/hematology	030x, 031x	<i>0872 and 0873 for Cell Processing:</i> Staff who perform cell processing services are the same staff who perform laboratory services. These revenue codes should be assigned to cost group 3350
0873	Storage and Processing after Receipt of Cells from Manufacturer	3350, laboratory/hematology	030x, 031x	
0874	Infusion of Modified Cells	4800, for intravenous therapy	0510, 0761, 0940, 0949	<i>0874 and 0875 for Infusion and Injection of Modified Cells:</i> Staff who perform infusion and injection of cell therapies are licensed nursing staff who are trained for this purpose. These staff are associated with therapeutic departments of the hospitals that furnish stem cell transplant services. These revenue codes should be assigned to cost group 4800.
0875	Injection of Modified Cells	4800, for intravenous therapy	0510, 0761, 0940, 0949	
0891	Special Processed Drugs – FDA Approved Cell Therapy	5600, drugs charged to patients	025x, 063x	<i>0891 and 0892 for Special Processed Drugs:</i> The NUBC designates this series as an extension of pharmacy, therefore these revenue codes should be mapped to cost center 5600.
0892	Special Processed Drugs – FDA Approved Gene Therapy	5600, drugs charged to patients	025x, 063x	



American Society for  
Transplantation and Cellular Therapy

The ASTCT believes there are multiple justifications for our proposed mappings:

- There are currently Category III CPT codes for CAR-T therapy services for cell collection (0537T) and cell processing (0539T) codes, which are billed utilizing the 087x revenue code series. CMS has assigned status indicator “B” for 0537T-0539T and has edits in place to line-item reject these services when billed on OPPS claims.

The lack of payment for these services should not preclude their being reported or tracked. In fact, in the CY 2019 OPPS Final Rule<sup>1</sup>, CMS stated, “...*there is no separate payment by Medicare for these steps in the manufacturing process. However, it will be possible for Medicare to track utilization and cost data from hospitals reporting these services, even for codes reported for services in which no separate payment is made. The CAR Tcell related revenue codes and value code established by the NUBC will be reportable on HOPD claims, and will be available for tracking utilization and cost data, effective for claims received on or after April 1, 2019.*”

Given CMS’ statement that these services can be reported by hospitals, and that they will be tracked, we believe it is important for CMS to assign appropriate cost centers to these revenue codes so that the expenses may be tracked accurately in the hospital cost report. Thus, regardless of the lack of separate payment for these Category III CPT codes under OPPS, we recommend CMS map the revenue codes associated with these CPT codes to the cost centers provided in the table above.

- CMS provides separate payment for the CAR-T therapy administration CPT code of 0540T via APC 5694. Therefore, the revenue codes under which this code may be billed (0874 and 0875) should, in particular, be appropriately mapped. Without this mapping, the providers’ expense to administer CAR T-cell therapy will not be included in the data used to develop the payment rate for APC 5694.
- The revenue series of 089x has been designated by the NUBC as an extension of pharmacy; thus, revenue codes 0891 and 0892, respectively reflecting FDA-approved cell and gene therapy, should be mapped accordingly.

The ASTCT requests that CMS update its files so that NUBC-designated revenue codes are reflected and mapped appropriately so that CMS and providers may avoid issues with inappropriate reporting of expense on hospital cost reporting, and to allow for accurate data collection on these services. These changes will reduce confusion for providers and maintain

---

<sup>1</sup> Federal Register / Vol. 83, No. 225 page 58906



American Society for  
Transplantation and Cellular Therapy

data integrity, particularly as services billed with these revenue codes increase over time under OPSS.

***We ask CMS to map the cell collection revenue codes 0870 and 0871 to revenue center 6000 (for clinic), the cell processing revenue codes 0872 and 0873 to revenue center 3350 (for laboratory/hematology), cell therapy administration to revenue center 4800 (for intravenous therapy), and revenue codes 0891 and 0892 to revenue center 5600 (drugs).***

### **III. Suggestion to Consider a Cap on Ambulatory Payment Classification (APC) Payment Rates**

In the Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS) final rule, CMS finalized its proposal to implement a cap on the decrease of the relative weight (RW) of a Medicare Severity-Diagnosis Related Group (MS-DRG) from one fiscal year to another. This finalized change would mean that the relative weight for any MS-DRG would not decrease by more than 10 percent in any one fiscal year. CMS also finalized a 5 percent limit on year-to-year decreases in hospitals' wage indexes. The ASTCT is grateful to CMS for these finalized changes; they are important modifications that will help hospitals maintain financial stability, improve the ability of low-wage index hospitals to manage their resources, and will indirectly improve the ability of providers to plan for and treat additional patients.

We request that CMS consider implementing a similar policy under the OPSS. Like the relative weights for MS-DRGs, the relative weights for APCs should also have a known maximum decrease in order to mitigate large negative changes from one calendar year to the next. Large fluctuations between payment cycle years can be particularly problematic for low-volume APCs. Specifically, there are certain procedures related to stem cell transplant and cell/gene therapy treatment that are low-volume, relative to other procedures under OPSS, and which face large declines in APC rates. For example, the CY 2023 OPSS proposed rule, one APC declined by over 40%. Certain services may be low volume because they are more intensive, or they are a newer procedure or service related to an innovative therapy. As under IPPS, predictability and stability of payment rates is important for providers' ability to plan and develop programs and continue to participate in research for new therapies in which to treat patients. CMS could perform an analysis similar to the one it utilized for IPPS in order to help find the right percentage to select and propose the identified percentage in next year's OPSS proposed rule for stakeholder commentary.

***We request CMS implement a cap to APC relative weight decreases from one year to the next, similar to the implementation of a 10% MS-DRG relative weight decrease cap in the FY 2023 IPPS final rule.***

---

The ASTCT thanks CMS for the opportunity to comment on the CY 2023 Outpatient Prospective Payment System (OPSS) proposed rule.