



American Society for
Transplantation and Cellular Therapy

October 5th, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8013
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

Dear Administrator Verma:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer the following limited comments on issues related to cellular therapy as part of our overall concerns about payment policies under the Hospital Outpatient Prospective Payment System (OPPS).

The ASTCT is a professional membership association of more than 2,200 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 have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current FDA approvals for Chimeric Antigen Receptor T-cell (CAR-T) therapy.

Comments CMS Made in the FY 2021 IPPS Final Rule Related to CAR-T Billing Instructions and Creation of a New Cost Center

In response to commenters' requests, we were pleased to see CMS state that it would consider the creation of new cost centers for revenue codes 891 and 892 in future rulemaking. As CMS is aware, the ASTCT has led the charge for this request for several years. We continue to strongly believe that separating cell and gene therapy product charges from drug revenue codes, 025x and 063x is critical if the agency intends to continue estimating provider costs by reducing billed charges to cost. **We continue to urge CMS to release new cost centers to capture this information as soon as possible.**



American Society for
Transplantation and Cellular Therapy

Additionally, with respect to commenters who expressed concerns about hospital charging practices, we truly appreciated CMS’ reiteration, not once, but twice in the Final Rule that, *“there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs.”*

Finally, in the FY 2021 IPPS Final Rule, CMS stated that it was out of scope for it to address commenters concerns about outpatient billing instructions related to reporting outpatient cell collection of cell processing charges on inpatient claims. We understand the agency felt it out of scope but believe the reason providers raised this question as part of IPPS is because of CMS’ own billing instructions in Medicare Special Edition (SE) article 19009 (published May 28, 2019, which updated information in the April 2019 OPSS Update Transmittal 4255) giving providers options for reporting cell collection and cell processing on *inpatient claims or outpatient claims*. As a result, we encourage CMS staff from both the inpatient and outpatient payment policy teams to work together to address the questions raised by commenters.

Specifically, we urge CMS to eliminate the confusion caused by the instructions it provided in SE 19009, and make the status indicator changes we describe below. By making these changes, CMS will not only eliminate confusion but also streamline data collection. Furthermore, changes will remove the administrative and financial burdens providers currently face with respect to providing cell collection and cell processing services.

We sincerely appreciate CMS’ consideration of our comments as it develops policies and program requirements for cell therapy in the coming years. This is critical, as we expect to see even more therapies approved at an even faster pace than what occurred from 2017-2020.

Status Indicator Assignment for CAR-T Category III CPT Codes for Cell Collection and Cell Processing

For the past two years, the ASTCT has submitted comments to CMS requesting the agency to change the status indicator for cell collection and cell processing services associated with CAR-T from status “B” to a separately payable OPSS status indicator. We presented this request to the Hospital Outpatient Payment (HOP) advisory panel two years in a row (2018 and 2019); in both cases, the panel agreed with our various request. Due to the Public Health Emergency and national crisis this year, we did not submit the issue to the HOP panel for its Summer 2020 meeting, in order to preserve time and resources—but that does not mean this issue is resolved for us or for our members.

In fact, the issue is likely to become worse as more products enter the market, a greater number of centers are certified, and access to these important therapies are available to more patients. Given these changes, there will be a greater number of instances in which cells are collected and processed. In the circumstances when the patient dies or becomes too sick to receive a CAR-T



American Society for
Transplantation and Cellular Therapy

infusion, the hospital receives *no payment of any kind*, neither from Medicare nor from the manufacturers, to cover the cost associated with collecting and processing the cells. When the cells are collected and processed and the hospital includes the charges on the outpatient claim for the date of service the services occur, the provider is not paid anything by Medicare.

It is for this reasons that the ASTCT again requests that, at a minimum, CMS assign status indicator “Q1” to CPT codes 0537T-0539T, and assign the codes to specific APCs: APC 5242 for 0537T (cell collection) and APC 5241 for 0538T and 0539T (cell processing).

These new CAR-T Category III CPT codes have been in use since January 1, 2019. Additionally, new CAR-T therapy revenue codes went live on April 1, 2019. As stated above, the April guidance was updated by CMS through SE article 19009, giving hospitals options for billing cell collection and cell processing described by CPT codes 0538T through 0539T, the new revenue codes, and the product code when the CAR-T infusion occurs in the outpatient vs. inpatient setting.

This billing guidance and the options CMS gives hospitals on reporting their charges is immensely confusing. It is especially confusing, given that the charges for these services when billed on outpatient claims are rejected as non-covered services but, if they are held and reported on an inpatient claim with a different date of service, they are accepted and counted towards the patient’s total covered billed charges that can impact final inpatient provider payment. The billing options CMS provides deviate greatly from normal coding and billing rules, but they also raise an important question – that is, how the same service can be simultaneously considered covered and non-covered depending merely on the *type of bill* it is reported on, not why or how the services are furnished.

Because of the ongoing confusion, along with inquiries from our members about why Medicare will not pay for hospital services when other payers do, and because of the anticipated approval of even more therapies in 2020 and 2021, we feel it is critical to raise this issue again with CMS.

The approval of additional therapies will place even more pressure on hospitals to absorb cell collection and cell processing costs for Medicare patients if CMS continues to assign status indicator “B” to these services. At some point, it will become completely untenable for hospitals to keep providing these services without reimbursement, particularly when the patient’s cells are collected but no cell therapy product is infused. Does CMS truly intend for hospitals to absorb these costs, which were incurred for patient-specific services? We note that hospitals will not even be able to hold and report these charges on an inpatient claim, as SE 19009 describes when there is no product administration and hence no inpatient CAR-T claim for MS-DRG payment. Even for prophylactic autologous blood collection services when the blood is not transfused, CMS allows providers to bill and be paid. We expect no less for these autologous cell collection and processing services.



American Society for
Transplantation and Cellular Therapy

In summary, for the reasons outlined above, the ASTCT once again respectfully requests that CMS change the status indicators for CPT codes 0537T- 0539T for cell collection and cell processing services from B to Q1. Doing so will allow these services to be eligible for separate payment on the condition that no other separately payable OPPI procedure (status indicators “S” or “T”) or visit (status indicator “V”) is provided on the same claim.

By making this change, CMS will:

- Enable hospitals to report and bill for these services in the same manner as all other services rendered to patients: in real time and on the most appropriate bill type based on whether the patient received inpatient or outpatient care.
- Enable hospitals to report the services performed at each separate outpatient encounter on individual claims, with the date of service, and the most specific CPT or HCPCS code and revenue code available.
- Provide separate payment for these services when no other separately payable service is reported.
- Allow for the consistent and accurate reporting of revenue codes 0891, 087x as created by the National Uniform Billing Committee (NUBC).
- Clarify the confusing billing scenarios presented in SE10009 and prevent providers from having to debate whether to deviate from standard billing practices.
- Allow the charges reported with revenue code 891 on an inpatient or outpatient claim to represent only the dollars associated with the cellular therapy product and not with the hospital services of cell collection or cell processing (those services will be reported separately with their own revenue codes).
- Allow charges for cell collection and cell processing to be treated consistently as covered charges regardless of whether they are reported on an outpatient or inpatient claim.

The ASTCT wishes to express its appreciation for the opportunity to provide these comments on the CY2021 Hospital Outpatient Prospective Payment System Proposed Rule. The ASTCT welcomes 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 black ink, appearing to read "Pavan Reddy".

Pavan Reddy, MD
Frances and Victor Ginsberg Professor of Hematology/Oncology
Chief, Division of Hematology/Oncology
Deputy Director, University of Michigan Rogel Cancer Center
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