ASTCT
American Society for
Transplantation and Cellular Therapy

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

October 20, 2023

SUBMITTED ELECTRONICALLY VIA MEARIS

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following letter regarding the upcoming FY 2025 IPPS Proposed Rule.

The ASTCT is a professional membership association of more than 3,700 physicians, scientists, and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy and hematopoietic stem cell-based gene therapies for genetic immune system and blood disorders.

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 very much rely on team care for the complex cancers and other disorders requiring hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T.

If CMS has any questions regarding these comments, please contact Alycia Maloney, the ASTCT's Director of Government Relations, at amaloney@astct.org.

Miguel-Angel Perales, MD
ASTCT President, 2023-2024
Chief, Adult Bone Marrow Transplantation Service
Attending Physician and Member
Division of Hematologic Malignancies, Department of Medicine
Professor of Medicine
Weill Cornell Medical College

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

ASTCT
American Society for
Transplantation and Cellular Therapy

Table of Contents

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

ASTCT DRG modification request

ASTCT physician members are responsible for providing the clinical care associated with CAR-T therapy and the other immunotherapies that map to MS-DRG 018. Product acquisition costs are the primary driver of CAR-T's high costs. The ASTCT notes that CMS' rate-setting methodology does not appropriately account for product acquisition costs—even with clinical trial cases set aside.

The ASTCT is submitting a formal DRG modification to request that a different national cost-to-charge ratio (CCR) be utilized in lieu of the drug CCR to reduce CAR-T product charges to cost for purposes of calculating the relative weight for MS-DRG 018 which will also lessen the significant reliance on outlier dollars seen today. We ask that the use of a different CCR remain in place until enough data have been accumulated for the agency to evaluate and implement a new cell and gene therapy CCR.

The drug CCR does not reflect CAR-T costs in MS-DRG 018 rate-setting

During the FY 2024 IPPS Proposed Rule Comment Period, the ASTCT requested that CMS utilize the "other" CCR to reduce CAR-T product charges (i.e., those in revenue code 0891) to cost for rate-setting as a means of addressing charge compression. CMS responded to the request in the FY 2024 IPPS Final Rule, stating: "*we do not believe it would be appropriate to utilize the 'other' CCR for CAR-T product charges associated with revenue code 0891. The categories assigned to the 'other' cost center are categorically not described by another cost center. This is not the case for CAR-T product charges, as the drug cost center describes the same type of product."*[1]

The ASTCT respectfully disagrees with CMS' assessment of the issue in its statement. The ASTCT is aware of numerous centers that accrue the CAR-T product acquisition cost in the cell lab and transplant department and not in pharmacy. Furthermore, CMS has not issued instructions to specifically reclassify CAR-T product acquisition costs to the drug cost center. Finally, for cost reporting years beginning on and after October 1, 2022, CMS has established the unique CAR-T cost center 78.

The ASTCT disagrees with CMS' statement that the *drug cost center describes the same type of product."* CAR-T products are fundamentally different than all other products within the cost center, as has been acknowledged by both the U.S. Food and Drug Administration (FDA) and the National Uniform Billing Committee (NUBC). As noted, many hospitals accrue CAR-T product expense elsewhere than the drug cost center and do not reclassify the expense to the drug cost center.

[1] Centers for Medicare & Medicaid Services, FY 2024 IPPS Final Rule, pg. 154

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Upon the first CAR-T approval in August 2017, the FDA issued a press release in which then-FDA Commissioner Scott Gottlieb, MD stated: "[w]e're entering a new frontier in medical innovation with the ability to reprogram a patient's own cells to attack a deadly cancer… New technologies such as gene and cell therapies hold out the potential to transform medicine and create an inflection point in our ability to treat and even cure many intractable illnesses."[2]

Since then, the FDA has not integrated CAR-T and other cellular therapy products into the routine drug approval processes overseen by the Center for Drug Evaluation and Research (CDER), which handles therapeutic medicines. Rather, cellular therapy products are processed and evaluated through the Center for Biologics Evaluation and Research (CBER), which has a specific charge to regulate cellular and human gene therapy products. In March of 2023, the FDA further formalized the differentiation of cellular therapy from traditional drugs with its announcement of a new cell and gene therapy "super office" and reorganization of staff to "enhance expertise in cell and gene therapies" and "address the substantial growth in the development of innovative, novel products."[3] As the ultimate regulators of all therapeutic products utilized by physicians or individuals, the FDA's deliberate separation of cell therapies from other drug products is significant.

CAR-T product costs continue to be several orders of magnitude higher than any other drugs utilized in the inpatient setting. In late 2023, WAC ranged between $420,000 - $465,000 for hospitals to acquire a single CAR-T product for a patient. Because CAR-T products are person-specific and cannot be utilized for anyone else, no bulk purchasing discounts are available. And, as CMS knows, 340B rates are not eligible for inpatient hospital use.

While some hospitals have modified their charging practices to partially account for the current CCRs used in CMS' payment and rate-setting calculations, many health systems are understandably reluctant to mark the product charges up commensurate with CMS' payment and rate-setting methodologies. Low-cost drugs are administered more commonly to inpatients, and hospitals tend to mark-up low-cost drugs at a very high rate; the resulting national drug CCR is, as a result, very low (0.18 for FY 2024). The ASTCT acknowledges CMS' explicit guidance in recent IPPS Final Rules (FY 2021 and FY 2022) that providers *should* charge in accordance with their CCRs. Nonetheless, providers find it very disconcerting to establish extremely high gross charges for products that cost more than $400,000 when the applicable drug CCRs are very low.

The NUBC also recognizes the difference between cell and gene therapy products. In September of 2018, the NUBC created dedicated revenue codes (087x and 089x) for cell and gene therapies, in recognition of the fact these products represent a unique class of drugs/biologics separate from existing pharmacy revenue codes 25x and 63x.[4] The NUBC perspective was reinforced by CMS' creation of a separate line (line 0078) in the cost report; this action signaled that the agency

[2] U.S. Food and Drug Administration; FDA approval brings first gene therapy to the United States, August 2017.
[3] U.S. Food and Drug Administration; Establishment of the Office of Therapeutic Products, March 2023.
[4] National Uniform Billing Committee; New Cell/Gene Therapy Codes, September 2018.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

views cell therapy products and their associated costs as being different from regular pharmacy costs, and wishes to isolate them.

The ASTCT does not expect the small proportion of hospitals that are certified to provide these specialized therapies and the small volume of patients who receive the therapy to impact the national drug CCR. In fact, the national drug CCR has decreased in the time since these therapies became available, the reliance on outlier dollars has grown and the fixed loss threshold has increased, as described further below. Therefore, we again respectfully request CMS to implement an intermediate solution to mitigate charge compression until the agency has the data needed to create a new, 20th cost center that can be used for cell therapies, separate from the drug cost center.

Significant outlier dollars are indicative of charge compression in MS-DR 018

The ASTCT's analysis of the FY 2022 claims data released with the FY 2024 rules showed **that 61% of MS-DRG 018 claims received substantial outlier payment**. The average outlier payment was just over $111,000, which is nearly 27% of the total payment received by hospitals for those cases.

It is critically important to note that the outlier payment for these claims occurred during a fiscal year *when NTAP was available* for several CAR-T products. This means that the proportion of claims that received outlier payment would have been even higher if NTAP were not available. For context, the proportion of claims that received outlier dollars in MS-DRG 018 exceeds the next-highest outlier proportion MS-DRG by 20% - 41% of claims within MS-DRG 001 (Heart Transplant with MCC) receive outlier payment, with an average payment of $106,000.

Outlier dollars' availability of is an important backstop for the IPPS system. **However, we believe it is neither reflective of CMS' intent nor appropriate for the agency to rely on outlier as a primary source of payment for most cases within a single MS-DRG.** By design, a hospital receiving outlier payment has already incurred a financial loss on that case (i.e., by absorbing the fixed loss threshold of more than $40,000 and by receiving only 80% of the balance beyond that threshold) and losses of this magnitude cannot be made up with thin margins on other cases. A 2022 analysis by the American Hospital Association (AHA) found that CMS pays 84% of Medicare IPPS cost on average; there is no opportunity to average away case losses of this magnitude.[5]

Our analysis of CMS' rate-setting data suggests that the average payment across CAR-T cases was $423,124—far less than product acquisitions costs, let alone the clinical care provided to CAR-T patients. Many CAR-T cases involve long and complex inpatient stays, as demonstrated by the geometric and arithmetic mean lengths of stay at 13.0 and 15.2 days, respectively.[6]

[5] American Hospital Association, *Fact Sheet: Underpayment by Medicare and Medicaid*, Washington (DC): AHA, 2022: https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid
[6] Centers for Medicare & Medicaid Services, *FY2024 IPPS Proposed Rule Home Page (Table 5)*

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

If more hospitals adjust their CAR-T charging practices based on CMS' guidance (albeit reluctantly), the percentage of cases receiving a substantial amount of their payment from outlier dollars is going to grow significantly. This growth will occur because charge compression means that MS-DRG 018's base payment does not cover the average cost of these cases. As an example, a hospital with an overall CCR of 0.25 that paid $400,000 for a CAR-T product would set a gross charge of $1.6 million for the CAR-T product; this estimate is based on simple reverse engineering and due the facility's knowledge of the NTAP and IPPS payment formulas. As CMS uses the national drug CCR (0.18) for rate-setting, however, the $1.6 million product charge is reduced to a drug cost of only $288,000—a number that is 28% lower than the actual acquisition cost of $400,000. This is why the unadjusted payment rate for MS-DRG 018 is below any of the products' wholesale acquisition costs (WAC). As noted, the ASTCT believes this issue will be magnified further in years when NTAP is unavailable for any CAR-T products, as is the case in FY 2024.

Finally, it is noteworthy that the outlier fixed loss threshold has increased dramatically in recent years, and it is at its highest ever level of $42,750 in FY 2024. If the charge compression issues driving the disproportionate utilization of outlier dollars by CAR-T cases are not remedied, we expect to see continued growth in the threshold—unfortunately, this result negatively impacts all hospitals, not just those providing CAR-T.

Use of an alternative CCR would decrease outlier dollars paid on CAR-T cases

The NUBC's creation of the unique revenue codes and CMS' creation of the unique cost center line in the cost report lay the groundwork for the creation of a new 20th cost center for cell therapies. The process of accumulating sufficient data via cost center 0078 (effective starting with fiscal years ending on or after 10/1/2022) will take several years, however. In the meantime, given the increasing proportion of CAR-T cases pulling significant outlier dollars from the rest of the PPS system, CMS should use the "other" CCR for these therapies.

Use of the "other" CCR rather than the national drug CCR would immediately mitigate the significant charge compression problem and result in a more-appropriate case cost for CMS to use in rate-setting for MS-DRG 018. A higher base payment would also instantly reduce both the *proportion* of cases receiving outlier payment as well as the *absolute amount* being paid out in outlier dollars for MS-DRG 018 cases. The fact that multiple stakeholders recognize that these therapies are fundamentally different from the products represented in the drug CCR should encourage CMS to think differently about this small population of products and cases within the IPPS.

If CMS does not support using the "other" CCR, we have two alternative approaches: 1) use each hospital's own overall operating and capital CCRs, or 2) use the average CCR utilized by hospitals that provide CAR-T. Either of these methods would enable CMS to reduce line-item billed charges reported under revenue code 0891 and mitigate charge compression.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Given the issues outlined in this modification request, the ASTCT believes that our proposed solution works within the bounds of CMS' current rate-setting system and presents a solution that would result in a more appropriate payment for MS-DRG 018. We request that CMS study all options in advance of the FY 2025 IPPS Proposed Rule and request stakeholder comments.

Medicare beneficiary need for cell and gene therapies will continue to increase

While CAR-T is an important and life-saving therapy, it is only one of many innovative therapies that will be provided by the ASTCT's member physicians and hospitals in the coming years. If these future innovative therapies face the same IPPS rate-setting and payment problems as CAR-T, our members are going to face very difficult decisions about delivering these services.

We appreciate that CMS has both acknowledged the need and taken explicit steps to improve the IPPS to support providers in their use of CAR-T. We also acknowledge that the agency is asked by multiple stakeholders to cover and pay for increasingly complex and innovative health care with CMS' limited resources.

Our member providers and hospitals face similar staff and resource constraints as they strive to provide innovative, potentially life-saving and/or life-altering therapies to Medicare beneficiaries with hematologic malignancies or hematologic disorders. In the FY 2019 Final Rule, CMS noted that *"it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased cost."*[7]

Yet, we note that it is equally inappropriate for CMS to expect hospitals to provide care at significant financial losses well beyond the IPPS averaging concept. Therefore, the ASTCT asks CMS to continue to analyze the IPPS and, specifically, MS-DRG 018, with respect to the clinical and scientific advancements that are increasingly outpacing the IPPS' constructs.

The ASTCT remains very interested in helping CMS explore the creation of a different set of MS-DRGs that can better accommodate cell and gene therapies. Potential methods include a "drug-intensive" MS-DRG system that mirrors the "device-intensive" APCs in the OPPS setting; using Medicare Advantage claims data to bolster volume in rate-setting; and implementing options for more frequent NTAP approvals.

The ASTCT appreciates the opportunity to submit this MS-DRG modification request and looks forward to engaging with CMS on the issue. Please contact Alycia Maloney, ASTCT Director of Government Relations, at amaloney@astct.org with any follow-up questions.

[7] Centers for Medicare & Medicaid Services, FY 2019 IPPS Final Rule.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733