ASTCT
American Society for
Transplantation and Cellular Therapy

September 17, 2021

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

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-1753-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the provision in the Calendar Year (CY 2022) Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule.

The ASTCT is a professional membership association of more than 2,600 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.

I. Status Indicator and Other Billing and Reporting Concerns for CAR-T Services

In the FY 2021 IPPS Final Rule, CMS stated that it was out of scope for the agency to address commenters' concerns about outpatient billing instructions related to reporting outpatient cell collection of cell processing charges on inpatient claims. Yet, CMS' billing instructions in Medicare Special Edition (SE) article 19009[1] gave options for providers to report cell collection and cell processing charges either on *inpatient claims*, *outpatient claims*, and/or with the charges included as part of *revenue code 0891*. These instructions were the basis for providers raising the question as part of their IPPS Proposed Rule comments.

While CMS does not discuss this issue in the CY 2022 OPPS Proposed Rule, despite our having raised concerns year after year, **the ASTCT once again urges the agency to eliminate the confusion caused by the instructions provided in SE 19009 and make the status indicator**

[1] Published May 28, 2019, as an update to the April 2019 OPPS Update Transmittal 4255.

changes we describe below. Given several recent and anticipated upcoming CAR-T product approvals, the number of CAR-T episodes of care provided to outpatients is expected to increase substantially—which will compound the impact of the existing confusing guidance.

By addressing this issue in the OPPS Final Rule and making the changes requested, CMS will eliminate confusion; streamline data collection; increase transparency around the provision of these services; and remove the administrative and financial burdens providers currently face with respect to providing cell collection and cell processing services.

A. Status Indicator Assignment for Category III CPT Codes for Cell Collection and Processing

In our review of Addendum B, the ASTCT was disappointed to note that CMS persists in its assignment of status indicator "B" to the CAR-T cell collection (0537T) and cell handling and processing services (0538T and 0539T), which results in these services being rejected when billed on outpatient claims. The ASTCT and other stakeholders have repeatedly requested CMS change this status indicator to either a separately payable or a conditionally payable status indicator so providers can receive payment for the services they provide.

The ASTCT recommends that CMS modify the status indicators for CAR-T cell collection and processing from "B" to "Q1" and assign the codes to the following recommended APCs:

- **APC 5242 for 0537T (cell collection) and**
- **APC 5241 for 0538T and 0539T (cell processing).**

As part of our previous efforts to resolve this issue, the ASTCT presented our status indicator change request to the Hospital Outpatient Payment (HOP) advisory panel in both 2018 and 2019. The panel agreed with our request in both cases, as noted in Medicare's Advisory Panel on Hospital Outpatient Payment's (HOP Panel) archives.[2]

Request Rationale

The CAR-T Category III CPT codes have been in effect since January 1, 2019. CMS' continued practice of making these services non-payable creates ongoing real and significant financial issues for hospitals, in addition to potential compliance concerns. Below, we describe each of the ASTCT's areas of our concern.

Uncompensated Services: Despite the objections of the ASTCT and others, both at the HCPCS Committee meeting in 2018, and in several written comments, leukapheresis and dose preparation procedures remain incorporated into the description of the CAR-T product HCPCS codes (Q2041, Q2042, Q2053, C9076). We continue to disagree with CMS when it characterizes

[2] APC Panel Archives, August 5, 2019. https://www.cms.gov/regulations-and-guidanceguidancefacaapc-panel-archives/2019-08-19

these activities as "steps in the manufacturing process" (the manufacturing occurs only when the cells are in the physical custody of the product manufacturer). The *payment* associated with these product codes does not include leukapheresis and dose preparation, since it is based off of the price of the CAR-T product alone—and that price is not inclusive of any cell collection and processing services. It is incorrect for CMS to point to the reimbursement for the product HCPCS codes as compensation for these outpatient services.

Furthermore, embedding services into the product HCPCS codes is also problematic since cell collection and preparation services may be rendered to patients who are ultimately not administered the product. Given the severity of illness in the CAR-T patient population, it is unfortunate, but accurate, to note that many patients who have completed the cell collection procedure pass away or otherwise become ineligible before they can receive the final infusion of the CAR-T product. Additionally, manufacturing failures or other issues that prevent infusion sometimes happen after successful cell collection from a patient. Data from the pivotal trials associated with currently FDA-approved products for the same or similar clinical indication(s) illustrate this issue:

- Product A: 344 patients underwent leukapheresis, 269 patients were infused[3]
- Product B: 165 patients underwent leukapheresis, 111 patients were infused[4]
- Product C: 111 patients underwent leukapheresis, 101 patients were infused[5]

While we cannot extrapolate any single trial's ratio of collections to infusions either to other products or to its own real-world treatment setting, the ASTCT's clinical advisors estimate that approximately 10 percent of patients who have cells collected for any type of CAR-T therapy do not receive the final product.

Per CMS' guidance in SE 19009, providers can report the charges for cell collection and processing services either as part of the product charge or on the administration claim. In the case of patient ineligibility or manufacturing failure, however, neither of these options is viable, since there is no product infusion. In these instances, the hospital receives *no payment of any kind* for the CAR-T services it has performed—neither from Medicare nor from CAR-T manufacturers—to cover the expense associated with collection and processing of the cells. While there is no payment recognition from CMS (i.e., separate payment or even packaged payment), the expenses for these services are included in the hospital's income statements and cost report but are not associated with the actual services furnished to OPPS patients, reported on claims, or used in OPPS rate-setting.

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[3] Abramson, J, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. *Lancet*, 2020; 396(10254):839-852. doi: 10.1016/S0140-6736(20)31366-0.

[4] Schuster SJ, Bishop MR, Tam CS, et al. Tisagenlecleucel in adult relapsed or refractory diffuse large B-cell lymphoma. *N Engl J Med*. 2019;380(1):45-56.

[5] Neelapu, S., et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. *New England Journal of Medicine*, 2017;377:2531-2544. doi: 10.1056/NEJMoa1707447.

The unreimbursed costs associated with the resources needed to collect, prepare, and process cells before they are sent for manufacturing are significant and will only accumulate as the CAR-T patient volume grows. For example, multiple new and anticipated near-term product approvals will expand the CAR-T treatment population to multiple myeloma, a significantly larger population than the lymphoma indications for the first approved CAR-T products. The cumulative number of cases in which patients are collected, and not infused— and for which the hospital receives no compensation—will quickly become material enough for hospital finance teams to be rightfully concerned about the continued provision of these services to Medicare beneficiaries.

Data Integrity: By not allowing these services to be reported, CMS fosters and perpetuates gaps in the claims and health data record. These gaps prevent CMS from gaining a complete record of all services being furnished to patients, which will impact its analysis of health equity and evidence-based care. As the number of cell therapy products grows, CMS will be missing data on tens of thousands of care encounters per year—which, by the nature of the therapy, are provided to some of the most critically ill of all of CMS' beneficiaries.

340B Compliance: The increase of outpatient CAR-T administration over time will trigger the use of 340B discounts for select CAR-T products at certain facilities. These hospitals have raised concerns about whether it is appropriate to include charges for cell collection cell processing services in the line-item charge for the cell therapy product reported with the CAR-T product HCPCS codes, despite this being an option CMS allows in SE 19009. Allowing hospitals to report cell collection and processing service charges as part of the product charge appears to go against CMS' requirement that hospitals must report charges consistently and reasonably, related to their acquisition cost. These reporting requirements are mandated by the Provider Reimbursement Manual's definition of charges (Part 1 Section 2202.4), and by states when reporting 340B drug discounts. It also seems to go against the NUBC's creation of separate revenue codes to reflect these services separately from the product charge, which has its own unique revenue code.

Inconsistency Across CMS Payment Practices and OIG Interpretation: The practice of bringing outpatient charges over to the inpatient bill when they occur more than three days prior (or one day prior for PPS-exempt providers) is hugely problematic, both from the perspective of hospital processes and the goal of ensuring consistency across CMS' payment methodologies. When these cell collection charges are reported on inpatient claims, CMS recognizes them as valid and allows the dollars to count towards NTAP and the outlier calculation, when applicable—yet, CMS rejects these same dollars, for the same services, under OPPS. The ASTCT does not understand why CMS *treats the same charges differently* simply because they are reported on an outpatient versus an inpatient claim. **We request that the agency share its rationale for this variation**.

Additionally, a 2014 Office of the Inspector General (OIG) report discussed expansion of the three-day payment window. Specifically, the OIG recommended that, "CMS seek legislative authority to expand the DRG window to include additional days prior to the inpatient admission"

so that Medicare and beneficiaries could realize millions of dollars in savings." The report explains that CMS has concurred with the OIG recommendations to include additional days in the DRG window in the past, yet both CMS and the OIG concurred that the three-day DRG payment window cannot be expanded or extended without legislation.[6] Given this, we do not understand why or how CMS is able to stand by the option in SE 19009 that allows providers to report CAR-T cell collection and cell processing charges associated with hospital outpatients that occur weeks prior to the inpatient administration service to be reported on the inpatient claim.

As a result, the ASTCT recommends that CMS modify its guidance in SE 19009 to no longer allow hospitals to put outpatient cell collection and processing charges occurring more than three days prior to an inpatient stay on inpatient claims or to report cell collection and cell processing charges as part of the product charge. Instead, we strongly urge CMS to revise its instruction in SE 19009 so that providers are instructed to report cell collection and cell processing services at the time they are rendered, using the appropriate codes and the applicable claim type.

To avoid these claims being rejected, we reiterate our request that CMS modify the status indicators for these codes:

CMS should assign status indicator "Q1" to CPT codes 0537T-0539T and assign the codes to the following recommended APCs:

- APC 5242 for 0537T (cell collection) and
- APC 5241 for 0538T and 0539T (cell processing).

With the Q1 status indicator, CMS would make separate OPPS payment when there is no other separately payable OPPS procedure (status indicators "S" or "T") or visit (status indicator "V") provided on the same claim.

By making the changes outlined above, CMS will:

1. 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 was a hospital inpatient or hospital outpatient.
2. 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 codes available.
3. Provide separate payment for these services when no other separately payable service is reported.

[6] Levinson D, *Medicare and beneficiaries could realize substantial savings if the DRG window were expanded*. Washington (DC): Office of the Inspector General, February 2014, OEI-05-12-00480, p. 20, paragraph 1.

4. Allow for the consistent and accurate reporting of revenue codes 0891 and 087x as created by the NUBC.
5. Eliminate the confusion and deviations from standard billing practices it created by giving providers various billing options in SE10009.
6. 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.
7. Allow charges for the covered services of cell collection and cell processing to be treated consistently as allowable and covered charges regardless of whether they are reported on inpatient or outpatient claims with the new revenue codes created by the NUBC.

B. Utilization of Specific Cost Centers

We were pleased that, in the IPPS Final Rule, the agency stated that it would consider the creation of new cost centers for revenue codes 891 and 892. This has been a consistent request from the ASTCT; we raise it here again because hospital cost centers are not only applicable to both inpatients and outpatients, but also impact rate-setting under both the OPPS and IPPS.

The National Uniform Billing Committee (NUBC) began utilizing separate revenue codes (i.e., 0891 and 0892) on April 1, 2019 to capture cell and gene therapies separate from other drugs/biologicals reported using drug revenue codes such as 0250 or 0636. **For this reason, the ASTCT continues to strongly believe that CMS should act likewise and separate cell and gene therapy product charges from other drug charges captured in the pharmacy cost center.** This will enable CMS to derive a more accurate estimate of cost from provider-billed charges, which is necessary if the agency intends to continue using its charges reduced to cost methodology for purposes of rate-setting. **Therefore, the ASTCT continues to urge CMS to release new cost centers as soon as possible**.

II. Telehealth and Temporary Policies Implemented During the Public Health Emergency

During the PHE, CMS implemented several policies related to telehealth. In this Proposed Rule, the agency requests comments on which of these policies are important and should be continued beyond the end of the PHE. Specifically, CMS request comments on providing behavioral health services via telehealth.

The ASTCT is supportive of the additional flexibility CMS is proposing for behavioral health telehealth services, and we request that CMS consider extending this type of flexibility to different types of services across additional areas of medicine.

As we commented in the CY 2022 MPFS Proposed Rule, telehealth services can be very useful for patients who are immunocompromised and must avoid exposure to COVID-19 and other

infectious agents that can be found in hospital settings. The patients treated by ASTCT's membership are particularly vulnerable while recovering from stem cell transplantation and/or being treated for graft-vs-host disease. Allowing flexibility in the use of telehealth services for situations that do not require in-person evaluation eliminates these patients' risks in the clinic and during transit to and from the hospital.

We also request that a patient's home should be allowed as an originating site for hospital outpatient departments (HOPDs) furnishing telehealth services. During the PHE, CMS has instructed hospitals that they may temporarily "relocate" the HOPD to provide services to a registered outpatient in their home. We recommend that CMS consider handling telehealth services provided to a patient where the originating site is "home" in the same way as it proposes to handle Category 3 telehealth services in the CY 2022 MPFS Proposed Rule. **The ASTCT recommends that CMS should allow telehealth via a home originating site to be covered and paid at least until the end of CY 2023, and then determine whether policies can be modified to enable HOPD services rendered via technology to patients in their homes after the PHE ends.**

As part of its request on telehealth, CMS also requested comment on whether it should maintain HCPCS code C9803 (which describes hospital outpatient specimen collection for COVID-19) after the PHE ends. **The ASTCT recommends that CMS retain this HCPCS code and make the payment associated with it permanent, since we believe it will continue to be used for the foreseeable future.**

III. Proposals on Price Transparency

In this rule, CMS makes additional proposals related to price transparency. These proposals include significant increases to the civil monetary penalties (CMP) for non-compliance with price transparency regulations. CMS also clarifies requirements around the use of online price estimator tools, plain language descriptions of "shoppable services," and posting of the machine-readable file of standard and negotiated charges, among other topics.

Due to the PHE and the fact that the payer price transparency rules have not yet been implemented, **the ASTCT recommends that CMS not introduce additional requirements or changes to price transparency requirements. Furthermore, we recommend that CMS delay enforcement of the requirements until the effective dates for price transparency policies for payers have passed.**

While the ASTCT understands the impetus behind price transparency requirements, we believe that achieving these policies' aims will require concerted effort from payers as well as hospitals. Treatment of hematologic malignancies is incredibly complex and may be modified multiple times throughout the course of care due to individual patient needs and their response to therapy. We cannot envision electronic tools *ever* providing accurate estimates to patients of their insurance coverage, financial obligations, lifetime maximums, and various financial assistance programs for which they may be eligible. This information requires *individualized financial counseling*.

Finally, we ask CMS to consider explicit exceptions for complex episodes of care for which online price transparency is not well-suited, such as hematologic malignancies. Attempting to force these tools to address complex patient situations will inevitably create misunderstandings, inaccuracies, and could ultimately prevent patients from seeking medically necessary care.

IV. Use of CY 2019 Claims Data for CY 2022 Rate-setting

The ASTCT agrees with CMS' proposal to utilize 2019 claims data as the base for CY 2022 APC weights under the OPPS. The ASTCT agrees with CMS that the PHE's impact on hospital services creates volume and case mix concerns for the CY 2020 data.

The ASTCT also supports CMS' proposal to provide up to four additional quarters of separate payment for 27 drugs and biologicals (and one device) for those products whose passthrough payment status would otherwise expire between December 31, 2021, and September 30, 2022. This is similar to how the agency extended New Technology Add-On Payments (NTAP) for an additional fiscal year. We appreciate this consistency across Medicare payment systems.

V. Changes to Beneficiary Coinsurance for Procedures Furnished During the Colorectal Cancer Screening Encounter

CMS proposes changes relating to the coinsurance due for colorectal cancer procedures that were originally planned as screening tests but that become diagnostic tests when the provider identifies the need for additional services, such as polyp removal. Beginning in CY 2022, the amount that Medicare beneficiaries are required to pay a coinsurance payment for these procedures, when furnished in the same clinical encounter, will be gradually reduced. As of the beginning of CY 2030, that amount will decrease to 0%.

We understand that this proposal is linked to changes in the statute. The ASTCT is grateful that both Congress addressed this issue, and that CMS proposes a way to implement it in the OPPS and the MPFS Proposed Rules. **We understand the barriers that coinsurance responsibilities present for patients and we support this change. The ASTCT asks CMS to clarify whether providers have the option to waive the co-insurance before the 2030 implementation date without generating compliance concerns.**

VI. Low-Volume APC Policy

The ASTCT supports CMS' proposal to establish a Low-Volume APC policy, which would be applicable to New Technology APCs, clinical APCs, and brachytherapy APCs. We agree that utilizing multiple years of data will increase accuracy in calculated rates and support the use of the greatest of the three cost statistics (e.g., arithmetic mean, median, or geometric mean).

VII. Radiation Oncology Model (ROM)

The ASTCT disagrees with CMS' proposal to implement the Radiation Oncology Model starting January 1, 2022. We add our voice opposing the model's implementation to the requests made by the American Hospital Association (AHA) and others, which have requested that CMS postpone implementation of the model. Unfortunately, hospitals are now dealing with yet another wave of the COVID-19 pandemic, and implementation by January 1, 2022, will cause additional burden for hospitals. We also recommend postponing because providers need additional clarification around appropriate billing, which CMS has not yet provided.

VIII. Request for Information on Health Equity Gap in Hospital Quality Programs

The ASTCT is glad to see that CMS issued a Request for Information (RFI) on closing the health equity gap in Medicare hospital quality programs in the CY 2022 OPPS Proposed Rule. Many of the questions in this Rule are similar to those posed by CMS in the FY 2022 IPPS Proposed Rule. We appreciate CMS' consistency in inquiring on how to close the health equity gap across payment systems.

Specifically, CMS requests comment and information about stratifying quality measure results by dual-eligible status and other social risk factors. As we commented in the IPPS Proposed Rule, the ASTCT recommends caution with respect to how the "other social risk factors" are quantified and utilized by CMS. As the agency is aware, myriad other factors affect quality but are not accounted for in dual eligibility, and an underserved populations in one geographic area or population may not be underserved in another. Also, dual eligibility as a marker does not capture the risks for patients who are in states that did not expand Medicaid under the ACA. **Therefore, the ASTCT reiterates that it is important that any and all stratified measurements are vetted, transparent, and rely on best analytic practices.**

CMS also solicits comments on collection of social risk factor data on hospital claims. **ASTCT supports the collection of risk factors but recommends that CMS consider using risk factor information that was collected from previous admissions and making it available to providers through the common working file (CWF).** This would be similar to the way admission dates are viewable for patients. This process would make the information available for subsequent admissions and reduce administrative burden on hospitals as well as patients having to be asked the same questions repeatedly.

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Thank you for the opportunity to provide these comments on the CY 2022 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,

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