ASTCT
American Society for
Transplantation and Cellular Therapy

June 24, 2019

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-1716-P; Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma:

The American Society for Transplantation and Cellular Therapy (ASTCT), formerly the American Society for Blood and Marrow Transplantation (ASBMT), is pleased to offer comments on the provisions affecting our members in the proposed rule governing the Fiscal Year (FY) 2020 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals.

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.

I. Summary of Comments

ASTCT members are committed to protecting appropriate patient access to CAR-T therapy and bone marrow transplant. The Society has been working closely with the Centers for Medicare and Medicaid Services (CMS) to improve Medicare payment policies for CAR-T therapy and is pleased the agency is considering policies to address the inadequate reimbursement for this potentially curative therapy. We recommend that CMS adopt the following changes to more appropriately reimburse for CAR-T cases both in FY 2020 and in FY 2021, if and when the agency develops a new MS-DRG for these cases.

- ASTCT supports CMS' proposal to increase the new technology add-on payment (NTAP) for all new technologies, but recommends that the agency increase the percentage from 50 percent to 80 percent rather than 65 percent as proposed for all NTAPs.

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- ASTCT recommends that CMS recognize the actual CAR-T product acquisition cost and use it to calculate NTAP and outlier **for CAR-T cases only**. This is how ASTCT suggests CMS implement a cost to charge ratio (CCR) of 1.0.

- ASTCT recommends that CMS eliminate CAR-T clinical trial claims in determining the relative weight of MS-DRG 016 and in future CAR-T rate setting.

- ASTCT urges CMS to use its authority to apply a different rate setting methodology in FY 2021 for CAR- T therapy in order to avoid the issue of charge compression of the product acquisition cost and to address the shortcomings of existing data. The Society offers our preliminary thoughts on this.

ASTCT also recommends that CMS make the following policy changes related to allogeneic bone marrow transplant:

- ASTCT encourages CMS to continue to examine and review the cost differential associated with the different types of donor cells used in allogeneic transplants for future rule making.

- ASTCT urges CMS to provide clear guidance to providers on the documentation, coding and billing of claims for bone marrow and stem cell transplants.

- ASTCT asks CMS to support policies that align with the reimbursement policies used for solid organ procurement and apply those policies to cellular transplantation, as outlined in the "Patient Access to Cellular Therapies Act of 2019."

II. FY 2020 CAR-T Policy

A. Current Medicare Reimbursement

Centers currently delivering CAR-T therapy acknowledge at the initiation of treatment that every Medicare beneficiary treated will result in a significant financial loss to the center. In last year's FY 2019 IPPS rulemaking, CMS assigned CAR-T cases to MS-DRG 016 with an unadjusted payment of $39,000 along with an authorized NTAP for both FDA-approved products, capped at $186,500. Each center is responsible for paying the full $373,000 acquisition cost for the product, resulting in many centers still losing over $100,000 on each case despite these payment changes. Centers recognize that FY 2020 will be the final year of the NTAP payment and are greatly concerned about future reimbursement for CAR-T therapy.

ASTCT has examined the FY 2018 MedPAR data and is concerned both about appropriate Medicare beneficiary access in FY 2020 and future rate setting. The volume of CAR-T cases is significantly lower than expected for a potentially curative cancer therapy. In the FY 2018 data, there were only 348 total CAR-T cases of which 201 of the cases were delivered by 37 PPS hospitals, accounting for 58 percent of the total claims. The remaining 42 percent of the cases were provided by 6 PPS-exempt hospitals. Our analysis of the PPS centers' data shows that there is a high volume of clinical trial cases with charges

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that are not representative of those non-clinical trial cases since they do not include the product charge. We recognize that CMS will trim out approximately 35 cases using its statistical trimming logic, leaving only approximately 40 CAR-T cases that would be used in rate setting. We provide our review of these cases and the average pharmacy charges in Appendix A. When looking more closely at the pharmacy charges that include the acquisition costs of CAR-T, ASTCT notes these pharmacy charges range anywhere from $3,729 to $6,082,928 (See Appendix B).

The Society recognizes that some of these charges would not be used in rate setting, but the large disparity in charges reinforces our concerns and those of the centers delivering CAR-T about current and future reimbursement for this therapy. Despite ASTCT's best efforts to educate centers about proper billing and coding practices, this data shows that not all centers are charging appropriately for the CAR-T product to capture the maximum NTAP available. These varying charging practices have resulted in payment shortfalls for some centers and will create problems for future rate setting for all centers. While charging practices may improve over time, we have provided a sampling of the current publicly available PPS hospital CAR-T Charge Description Master (CDM) charges that shows the high variability in hospital charges. Based on this review, ASTCT remains concerned about CMS' current and future payment policies for CAR-T. Our recommendations that follow are focused on addressing this disparity and preserving patient access to CAR-T therapy.

B. Evaluation of CMS Proposals

In the proposed rule, CMS outlined several policies that either would apply to CAR-T or were specific to CAR-T for FY 2020:

- Proposal to increase NTAP cap to 65 percent for all new technologies;
- Continue NTAP for CAR-T in FY 2020; and
- Continue assigning CAR-T cases to MS-DRG 016.

The agency also requested comment on several policies that could be applied in FY 2020:

- Uniform add-on payment for CAR-T NTAP;
- Utilization of the CCR of 1.0 for CAR-T NTAP and for CAR-T outlier; and
- Changes to the TEFRA caps for PPS-exempt centers.

For FY 2021 and beyond, CMS requested comments on issues related to future rate setting for a new CAR-T MS-DRG, as well as alternative payment models for CAR-T.

ASTCT examined these proposals and requests for comment through the lens of several policy objectives. Protecting appropriate patient access to this therapy is our primary concern. This includes ensuring that centers not currently delivering this therapy because of financial rather than clinical concerns can afford to do so in the future. As evidenced by the data, a small number of centers continue to treat the majority of patients.

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Some of our members have shared that their centers are at capacity in their CAR-T programs because of the high demand as they are the only center in the area delivering this therapy. Many patients and their caregivers are forced to relocate to be closer to a center, resulting in significant additional costs to the patient and potential loss of wages for their caregivers. The fact that there are a limited number of certified centers providing the therapy may also result in wait times for patients, many of whom cannot afford to wait. ASTCT strongly believes that a center's choice to provide CAR-T to patients should be a clinical decision, not a financial one.

ASTCT is also committed to patients being treated in the appropriate site of service. Decisions about site of service should be clinical, not based on reimbursement. Many of the patients receiving CAR-T are critically ill and should only be treated at the inpatient setting. Clinicians must also consider potential adverse events when determining a patient's course of treatment, such as cytokine release syndrome. There is no room for reimbursement considerations to be included in this calculus.

ASTCT appreciates CMS' continued interest in developing an improved and sustainable payment policy for CAR-T therapies, as well as continued engagement with us on this topic. We recognize the agency's concerns about overpayment for CAR-T and CMS' interest in working within its existing payment structure; our evaluation of policies for FY 2020 and beyond considers these factors.

C. ASTCT'S FY 2020 PAYMENT POLICY RECOMMENDATIONS

ASTCT has four primary recommendations to improve CAR-T payment policy in FY 2020. These requests are consistent with the policy recommendations that the Society has previously made to the agency.

1. Utilize the actual CAR-T product acquisition cost to calculate NTAP and outlier for CAR-T cases only.

ASTCT first proposed that CMS implement the concept of a CCR of 1.0 for CAR-T to ensure that differential provider charging and mark-up practices would not impact a hospital's ability to obtain the maximum NTAP in our September 2017 letter on CAR-T payment policy.[1] Using this concept would enable CMS to recognize the actual product cost for CAR-T rather than estimating the cost through the typical process of reducing billed charges to cost using the hospital's overall CCR (for purposes of NTAP and outlier payment). In the proposed FY 2020 rule, CMS requests comment on, but does not propose, applying a CCR of 1.0 to calculate NTAP and outlier. The agency provided the following example of the application of a CCR of 1.0:

> For example, and as described in the FY 2019 IPPS LTCH PPS final rule (83 FR 41773), if a hospital charged $400,000 for the procedure described by ICD-10-PCS procedure code XW033C3, the application of a hypothetical CCR of 0.25 results in a cost of $100,000 (=$400,000 * 0.25) while the application of a hypothetical CCR of 1.0 results in a cost of $400,000 (=$400,000 * 1.0).[2]

[1] https://higherlogicdownload.s3.amazonaws.com/ASBMT/UploadedImages/6cfeff77-6acc-46fe-8d3d-db9dddebe47a/ASBMT_Letter_CMS_CAR_T_9_6_17_Final.pdf
[2] 84 Fed. Reg. 19182, May 3, 2019.

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ASTCT appreciates CMS including this example but wishes to clarify that we never intended for a CCR of 1.0 to be applied directly to the billed line item product charge as shown in CMS' example. The Society acknowledges CMS' concerns about a literal interpretation of CCR of 1.0 being applied to billed item charges and wishes to reassure the agency that this was never our intent as we recognize the program integrity concerns that interpretation could raise. Instead, the Society has always proposed that the CCR of 1.0 concept serve as a proxy for the product acquisition cost. Until the April 2019 National Uniform Billing Committee (NUBC) updates, there was no other way to isolate either the CAR-T product charge or identify actual acquisition cost from the claim. ASTCT always intended that CMS recognize the actual product acquisition cost in the following manner:

1. Compute the "Patient Care Cost" Only- Subtract the line item drug charge reported in new revenue code 0891 from the total inpatient charges on the CAR-T claim. Multiply the result by the hospital's overall CCR to get the calculated patient care cost.
2. Derive the new "Total Case" Cost- Add the calculated patient care cost to the CAR-T drug cost that results in the newly calculated cost.
3. Use the newly calculated cost as the starting point in the NTAP and outlier calculations.

ASTCT requested that the concept of a CCR of 1.0 be applied in conjunction with the newly approved NUBC revenue code 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and value code 86 (Cell/Gene Therapy Invoice Cost). By using the actual product cost in its various calculations, centers would receive the full NTAP regardless of their charging practices. This is what we hoped to convey in the ASTCT-American Society of Hematology (ASH) letter dated November 1, 2018[3] and in our subsequent discussions with the Center for Medicare leadership in January 2019 when we were aware of the NUBC changes effective April 1, 2019:

> For the FY 2020 IPPS cycle, the Societies request the implementation of a CCR of 1.0 applied to the CAR-T product, in conjunction with the implementation of the NUBC changes detailed previously. Using the NUBC claim changes with a CCR of 1.0, CMS can continue to utilize the current NTAP and outlier payment methodology in FY 2020 while creating a pathway for PPS providers to gain the maximum NTAP payment without the transparency concerns currently associated with reporting the product charges. The Agency proposed a CCR of 1.0 for the product in the FY 2019 IPPS Proposed Rule but did not finalize a solution, citing concerns about how it would be implemented without additional detail on the claims.
>
> We believe CMS can again consider a CCR of 1.0, given the implementation of the NUBC changes, and do so in a manner that is more closely aligned with CMS' perceived intent – one that is based on reported actual acquisition costs, using Value Code 86. This ensures that no dollars associated with a mark-up would be included or paid using the NTAP or outlier formulas, which protects CMS from possible over-payments and helps hospitals avoid the use of high mark-ups.

[3] https://higherlogicdownload.s3.amazonaws.com/ASBMT/UploadedImages/4ce8a833-1ad9-4e62-9908-6c459f584ff1/ASBMT_ASH_CAR_T_Solutions_FINAL_11_1_2018.pdf

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> Our recommendation is for CMS to replace the provider's line item CAR-T product billed charge (as detailed on the inpatient claim with a HCPCS code and revenue code 0891) with the actual acquisition cost reported with new value code 86 in the computation of the NTAP and the outlier. This will provide CMS with transparent information about product acquisition cost, and any discounts, which meets the agency's goals and ensures that it has accurate data for future rate setting.[4]

ASTCT again urges CMS to use this concept, whether it is characterized as implementing a CCR of 1.0 or using actual product acquisition cost in its calculation of both the NTAP and outlier for CAR-T products. The Society believes this policy continues to be the most equitable way to improve CAR-T reimbursement policy for both centers and CMS. It will neutralize mark-up practices by improving reimbursement for centers unwilling or unable to reverse engineer CMS' NTAP formula to mark-up appropriately as seen in hospitals' publicly available CDMs. Under this approach, CMS will collect actual cost data, which will be far more accurate than the agency's current methodology of reducing charges to estimate product costs. This approach will also address the serious issue of charge compression that we are currently seeing in the claims data. ASTCT is confident this solution has the potential to expand access, and importantly, prevent CMS from making overpayments to hospitals with extraordinary markups. We have reached this conclusion after modeling a variety of scenarios trying to isolate the impact of CMS' existing and proposed policies, as well as policies on which comment was requested, in Appendix D.

Using the concept of a CCR of 1.0 in the manner described above will eliminate the use of the outlier payment pool to make up for the shortfall in the NTAP . ASTCT has raised concerns about the impact on the outlier pool that may result from extraordinary mark-up practices. It will be mitigated by this approach because the actual product cost will be used in the calculation. Furthermore, CMS' reimbursement formulas will remain intact, only necessitating one change that can be applied to both NTAP and outlier in its calculations.

Another benefit of this approach is that it is unique to CAR-T therapy since this therapy has its own revenue code and value code to help isolate both the product charge and the actual product acquisition cost. This is not available to other NTAPs today. It is possible that we may see more revenue codes and/or value codes that would allow this methodology to be applied to other products in the future.

ASTCT recognizes that the reporting of value code 86 is not currently mandatory, and **we request that CMS require it be reported on all CAR-T claims.** The value code will allow CMS to see the actual acquisition cost for cellular and gene therapies. The cost would equate to $0 for clinical trial cases, allowing CMS to easily identify those cases that currently may not be properly identified on the claim, which will then prevent payments for NTAP on that case. It will also provide visibility for acute lymphocytic leukemia cases with the higher acquisition cost of $475,000, which we recognize may only occur a handful of times in the Medicare data, such as for dual-eligible cases. The acquisition cost may

[4] *Ibid.*

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eventually be an amount lower than $373,000 if manufacturers start providing discounts on the product or an applicable 340B discount is applied in cases where a patient is admitted after receiving the infusion as an outpatient. All of this data would then be available for future rate setting.

ASTCT, ASH and the American Hospital Association (AHA) have all previously requested that CMS require centers to report value code 86 on CAR-T cases and we are again requesting the agency require this. The agency can add an edit between value code 86 and the CAR-T ICD-10-PCS procedure codes to ensure that the value code is being reported. When this edit recognizes an incomplete claim, centers would then have an opportunity to resubmit the claim with the value code field completed. We are confident that any administrative burden placed on the center will be outweighed by the value of the data collected and the potential to improve future rate setting. However, ASTCT recognizes that if CMS were to require that the value code be reported as of October 1, 2019, the agency would only have a very limited set of claims with the product acquisition cost included for FY 2021 rate setting since reporting the value code would have been optional until the start of FY 2020.

This proposed solution will allow CMS to recognize and reflect the actual acquisition cost of the therapy in its calculations. This will improve reimbursement for centers in a manner that may increase patient access while the agency considers longer term solutions to reimburse for gene and cellular therapies, like CAR-T, that are unique to each patient.

The Society also considered recommending a uniform NTAP for CAR-T, another policy on which CMS requested comment but did not formally propose. Our analysis of this policy can be found in Appendix D. ASTCT determined that supporting CMS' own policy of increasing the NTAP cap, which is discussed in detail below, paired with the use of actual product acquisition in the NTAP and the outlier calculations is a better policy solution than what CMS proposed since it is based on CMS' proposal and improves upon it for both NTAP and outlier.

2. Increase the NTAP cap to 80 percent for all new technologies and continue the CAR-T NTAP in FY 2020

ASTCT applauds CMS for proposing to increase the NTAP cap for all new technologies from 50 to 65 percent. However, the Society does not believe this proposal goes far enough to encourage hospitals to adopt new technologies, particularly very expensive therapies like CAR-T. This is because there are currently no sustainable models for payment in the long term. As such, ASTCT encourages CMS to increase the cap to 80 percent, as a logical extension of the original proposal. We believe that increasing the NTAP to this level strikes the appropriate balance between encouraging hospitals to adopt new, expensive therapies, like CAR-T, and recognizing that CMS does not want its policies to encourage such high prices for new technologies.

The Society recognizes CMS' responsibility to be stewards of the Medicare trust fund but increasing the NTAP cap by an additional 15 percent should not pose a financial problem for CMS. Historically, the agency has not paid anywhere close to the full NTAP, which has been capped at 50 percent since its implementation in 2001. The AHA provided an analysis in its FY 2019 IPPS comment letter that showed

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that to date, payments have been 33 percent less than the agency's targets. These financial reserves provide CMS with the ability to increase the NTAP cap to 80 percent for all new technologies. If the agency were to find that the increase to 80 percent was financially unsustainable, it could again adjust the percentage downward in future regulation. CMS did not propose to remove the "lesser of" language from the NTAP regulation, therefore only centers that mark-up appropriately would receive the full NTAP.

ASTCT also recommends that CMS extend the CAR-T NTAP as proposed for FY 2020. Please refer to Appendix D to review all of the payment options that the Society considered in formulating our recommendation.

3. Continue to Assign CAR-T Cases to MS-DRG 016

CMS proposes to continue to assign CAR-T cases to MS-DRG 016 in FY 2020. ASTCT agrees with this proposal and urges the agency to finalize it. Based on the available data discussed above, the Society believes it is premature to establish a new MS-DRG for CAR-T. The FY 2018 MedPAR data raises concerns about data accuracy. CMS will be setting a precedent for how it sets a MS-DRG for a cellular therapy when it engages in rate setting for CAR-T. Given the access concerns that already exist, a more permanent payment policy must be based on the best available data.

The data currently available to the agency is limited to a small number of cases and is fraught with inconsistencies. ASTCT has repeatedly raised our concerns about collecting consistent and accurate data on CAR-T cases. CMS must address the significant charge compression that is present even in claims that are coded accurately. The agency must also provide clearer coding and billing guidance to get the necessary data to develop an accurate and equitable MS-DRG. The use of the revenue code and value code will help improve the data reported to CMS. The Society will also address other potential coding changes later in these comments that will help improve the quality of the data for CAR-T cases.

In the meantime, while CMS continues to assign CAR-T cases to MS-DRG 016, ASTCT recommends that CMS eliminate the CAR-T clinical trial cases in the calculation of that MS-DRG's weight. CMS requested comment on this policy proposal with respect to future rate setting. Clinical trial claims do not accurately reflect the cost of CAR-T therapy because the therapy itself is not charged to the institutions in these cases and thus should not be used in current or future rate setting for CAR-T therapies.

4. Other Coding Recommendations for FY 2020

ASTCT outlined how CMS should use the NUBC-approved revenue code 0891 and value code 86 in our discussion above. We also recommend that CMS make the following coding changes, which will improve the accuracy of the data being collected that can be used in future rate setting:

- ASTCT requests that CMS have the CAR-T product's National Drug Code (NDC) printed in the description field on the inpatient claim, as this will provide visibility about which CAR-T product was used. This will allow the agency to have data on which product is being administered more frequently and provide information on outcomes that is not currently available.

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- ASTCT urges CMS to create a dedicated cost center for CAR-T in the cost report as soon as possible. This information is critical to develop a 20th national cost group for cellular therapy that may be necessary for future rate setting.

III. CAR-T POLICIES FOR FY 2021 AND BEYOND

ASTCT appreciates CMS' requests for comment on how to develop a MS-DRG for CAR-T therapy in FY 2021. This discussion represents our preliminary thinking on this topic and the Society will be providing more information prior to the November 1 deadline to request a new MS-DRG.

In reference to developing a new MS-DRG for FY 2020, CMS states that the FY2018 MedPAR data file "does contain some claims that include those procedure codes that identify CAR T-cell therapies, the number of cases is limited, and the submitted costs vary widely due to differences in provider billing and charging practices for this therapy. Therefore, while these claims could potentially be used to create relative weights for a new MS-DRG, we do not have the comprehensive clinical and cost data that we generally believe are needed to do so."[5] ACTCT agrees with the agency's conclusion not to develop a new MS-DRG for FY 2020 based on our review of the same data. However, the Society is extremely concerned that the FY 2019 MedPAR data will not be significantly improved based on our review of centers' publicly available charge masters and feedback from centers.

ASTCT strongly encourages CMS not to engage in rate setting as usual for CAR-T therapy in FY 2021. Based on the agency's requests for comment on how to set the relative weight of a new MS-DRG, whether to incorporate a percentage of the products' average sales price (ASP), and how to apply the adjusters, it appears CMS recognizes that it would be exacerbating existing patient access issues by doing so. The agency should instead exercise its broad authority under §1886(d)(5)(I)(i) of the Social Security Act to "provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate." ASTCT recognizes CMS has previously stated that "…exceptions and adjustment authority should not be used routinely in the IPPS system",[6] but determined that the specific circumstances were "unique"[7, 8, 9, 10, 11] or "extraordinary"[12]. Rate setting for CAR-T is both unique and extraordinary considering this is a new branch of medicine that requires CMS to use its authority to make adjustments to the rate setting process.

In this letter, ASTCT has already discussed how differential charging practices are currently affecting reimbursement, as well as our recommendations to neutralize these practices and expand patient access in FY 2020. Any changes CMS makes for FY 2020 will be too late to improve the FY 2019 MedPAR

[5] 84 Fed. Reg. 19181, May 3, 2019.
[6] 78 Fed. Reg.50953, August 19, 2013.
[7] 69 Fed. Reg. 49104, August 11, 2004.
[8] 71 Fed. Reg. 48071, August 18, 2006.
[9] 78 Fed. Reg. 50953, August 19, 2013.
[10] 81 Fed. Reg. 57058, August 22, 2016.
[11] 82 Fed. Reg. 38188, August 14, 2017.
[12] 69 Fed. Reg. 49104, August 11, 2004.

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data for FY 2021 rate setting. Specifically, if CMS requires it to be reported on October 1, 2019, value code 86 will be visible in FY 2020 MedPAR data, but not in the FY 2019 data. For this reason, we are especially concerned about how CMS will engage in rate setting for FY 2021. We will see disproportionate amounts of charge compression that will impact the new MS-DRG's relative weight if CMS applies its normal rate setting process to create a new MS-DRG for CAR-T. A new MS-DRG developed in this manner will result in significant underpayment of a MS-DRG for CAR-T that will further limit patient access. Additionally, CMS will have to address the issues of what adjustments to apply to a CAR-T MS-DRG that includes payment for both the patient care and the product cost.

We urge CMS to exercise its authority to engage in a different rate setting process for FY 2021 and beyond as it considers developing a new CAR-T MS-DRG.

ASTCT recommends that CMS create a new MS-DRG for patient care costs and a separate MS-DRG or payment group for the product cost. CMS can employ the averaging process that is the foundation of its PPS systems for both payment groups. We believe there are several benefits to this approach.

- Our clinicians are only able to control the patient care costs for CAR-T therapy and other cellular and gene therapies, not the product cost that overwhelms the patient care cost in a way never seen before in the DRG system. It would be appropriate for CMS to utilize its authority to limit the base MS-DRG payment to the patient care portion only and to allow for a separate payment group or MS-DRG for the product.

- CMS can bypass how to handle adjustments differently if it simply creates a patient care MS-DRG that is appropriately adjusted using its normal methodology for wage-index, indirect medical education (IME) and disproportionate share (DSH), and a separate product MS-DRG that is not adjusted.

- Neither CMS nor providers will have to worry about significant over-or-underpayments that could otherwise result if the entire product cost is built into the MS-DRG and adjustments are applied normally.

- CMS would have some flexibility in how to create one or more separate payment groups for various products over-time that reflects some form of averaging of either manufacturer reported ASPs or value code 86 data once available.

Ideally, CMS would be able to create product payment groups relying on the data reported in value code 86 that will provide visibility of actual product acquisition cost. CMS will not have this data for FY 2021 since the FY 2019 claims data is not likely to reflect the usage of this voluntary new claim field. Therefore, for FY 2021 rate-setting CMS would have to rely on the product's ASP for obtaining acquisition cost to use in creating a new product cost group.

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Approximately six months of FY 2019 MedPAR data will include revenue code 0891 to isolate the CAR-T product charge assuming all providers and Medicare Administrative Contractors began reporting this required revenue code on its effective date of April 1st. CMS will have to rely on multiple data sources, make certain assumptions, and likely set aside certain claims in order to come up with the best payment approach for CAR-T if the agency departs from its usual rate setting methodology for FY 2021. The agency should be able to fully rely on claims data for rate-setting purposes in FY 2022 if it does indeed begin requiring value code 86 as we are requesting starting in FY 2020.

Finally, CMS did request comment on excluding clinical trial claims from rate setting. As discussed above, ASTCT previously recommended that these claims be omitted from determining the rate of MS-DRG 016 for FY 2020 and recommends that they be excluded when setting a new MS-DRG for CAR-T using the same rationale.

ASTCT recognizes that CMS will be setting a precedent for how to develop a MS-DRG for gene and cellular therapies that will be approved in the future, forcing the agency to consider how to exercise its discretion in a manner that will reasonably be applied to those therapies as well. The Society reminds CMS that CAR-T itself is unique in that it is potentially curative for patients who have exhausted all other options. Our members remain concerned that Medicare reimbursement policies may slow the rapid pace of innovation in this area if the policies do not reflect the manner in which innovation is changing the practice of medicine. ASTCT is confident that a new MS-DRG can be designed such that it protects both patient access and CMS' interests as we continue to explore how to best pay for CAR-T and other gene and cellular therapies. These continued conversations around high product acquisition costs may be changed by potential alternative payment models.

IV. CAR-T REIMBURSEMENT FOR PPS-EXEMPT CENTERS

CMS requested comments on how improve the process for reimbursement under the Tax Equity and Fiscal Responsibility Act (TEFRA) in light of the current environment, especially considering issues such as CAR-T. ASTCT has focused these comments on policies applicable to PPS institutions, but recognizes that PPS-exempt centers that operate under TEFRA are responsible for half of the CAR-T cases. As such, the Society supports the request by the Alliance of Dedicated Cancer Centers (ADCC) for CMS to implement a prompt and automatic adjustment for cancer hospitals providing CAR-T therapy in recognition that it is a reasonable cost directly related to patient care under TEFRA.

V. ALLOGENEIC BONE MARROW TRANSPLANT

ASTCT appreciates that CMS included an analysis in the proposed rule on the impact of splitting MS-DRG 014 into two separate groups based on if related or unrelated donor cells were used in transplant cases. We appreciate that CMS continues to work with the National Marrow Donor Program (NMDP) to examine the cost differences of providing stem cell transplants based on the type of donor cells, which is essential to ensure appropriate rate setting and reimbursement for allogeneic transplants in future rule making.

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Stem cell transplant cases present more complex billing and coding issues than other types of services. Therefore, the Society asks CMS to provide additional clarification and guidance for providers on coding and billing practices for allogeneic transplants. In particular, we applaud CMS for reviewing the Claims Processing Manual to ensure that the language reflects change requests and additional agency guidance. As part of this review, we echo NMDP's request to issue instructions on cost capture for the dedicated cost center 77, created to capture donor search and cell acquisition costs. CMS created this cost center in January 2017 but has not provided any guidance to hospitals to date. We would also ask that CMS review Section 231.11.1 of Chapter 4 of the Medicare Claims Processing Manual, which includes: "Physician pre-procedure donor evaluation services" as an example of acquisition costs for allogeneic HCT. It is our opinion that these costs should not be reported as facility costs in cost center 77, and that this may conflict with the instructions given to providers in transmittal 1805, which instructs providers to bill physician services for stem cell donors which would include "physician pre-procedure donor evaluation services" to MACs for Part B payment under the recipient's name and number. Since the agency is taking the time to review its manual, it would be a good opportunity to provide clarification and correction on these additional issues.

Medicare-eligible patients receiving a blood or marrow transplant account for 16 percent of all stem cell transplants in the United States and continually increases ever year. ASTCT has committed physicians, researchers, and other healthcare professionals to continue to develop and administer these innovative treatments. Under current law, hospitals receive a single payment that combines both the cost of acquiring cells for transplant with inpatient hospital costs incurred during transplant procedures. Currently, transplant centers are losing thousands of dollars on each Medicare beneficiary they treat, and many providers can no longer afford to provide these transplants due to inadequate reimbursement.

To address this issue, Senators Richard Burr (R-NC), Debbie Stabenow (D-MI), Sherrod Brown (D-OH) and Tim Scott (R-SC), along with Representatives Ron Kind (D-WI), Kenny Marchant (R-TX), Gus Bilirakis (R-FL) and Doris Matsui (D-CA) have introduced legislation to ensure that hospitals receive adequate Medicare payment for the acquisition of hematopoietic stem cells. The Patient Access to Cellular Therapies Act (the PACT Act) amends the Social Security Act by including stem cells as part of the inpatient hospital services costs similar to that of solid organs. This would ensure that transplant centers receive equitable reimbursement for the acquisition of bone marrow and cord blood cells.

ASTCT asks CMS to highlight the passage of the PACT Act as an administration policy, which would garner further bipartisan support for this important issue.

VI. RECLASSIFICATION OF SECONDARY NEOPLASM DIAGNOSIS CODES

The Society would also like to take the opportunity to address the massive secondary diagnosis code designation changes that CMS proposed in the rule. Nearly 1,500 codes are proposed to have their severity classification changed, and most are proposed to have that designation downgraded. Among the changes are the downgrading of 767 neoplasm codes from complications and comorbidities (CC) to

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Non-CC status, including codes for lymphomas. These proposed changes for neoplasms represent more than half of the severity level changes.

Our review of CMS' supplemental data file released with the Proposed Rule shows a number of inconsistencies that merit closer attention before the agency proceeds with any reclassification of neoplasm codes as well as many others. In the rule CMS describes its methodology to assess resource utilization associated with all of the secondary diagnosis codes proposed to be downgraded from CC or MCC to non-CC or CC to see if the presence of the code represents increased resource utilization, average resource utilization, or less than average resource utilization.

Our understanding is that CMS assigned scores to each code and codes with values closer to 1.0 represent average resource utilization that approximates or is closer to cases designated as non-CCs, while values closer to 2.0 or higher, indicate that the presence of the secondary diagnosis code under review involved more resource utilization - in line with a case classified in as a CC or MCC.

Given this, we can understand why CMS might propose to downgrade diagnosis codes with a computed resource utilization value of 1.2, 1.0 or below. Perhaps even codes with slightly higher values such as 1.4 or 1.5 could merit a downgrade, but we cannot understand why CMS would recommend downgrading codes that it computed resource utilization values greater than 1.5; including values of 2.0, 3.0 and higher. CMS' own explanation in the rule indicates that a C1 value of 1.8 or higher for a secondary diagnosis means that for the subset of patients who have that secondary diagnosis code (and no other secondary diagnosis present, or only non-CC secondary diagnoses), the impact on resource utilization of the secondary diagnosis is closer to a CC than a non-CC. Our cursory review of the accompanying data file reveals well over one hundred codes that have resource utilization values above 1.8, and even more above 1.5.

ASTCT understands why CMS proceeded with proposing downgrading these codes. We are especially concerned with the neoplasm codes, which our clinicians have a great deal of experience using.

For example, a patient with a lymphoma diagnosis secondary to another unrelated reason for admission will require a different level of attention and care. Patients with lymphoma are often receiving treatment that could leave them immunocompromised, or with low blood counts and in need of greater supportive care. Understanding if a patient with lymphoma can safely be treated for other unrelated illnesses or injuries often involves additional laboratory or imaging services. Procedures that might be routine for a patient without any kind of hematological malignancy may involve far greater risk and may not be tolerated by patients who have been in active treatment for lymphoma. In addition, a patient may continue to receive treatment for their lymphoma while in the hospital. As such we do not feel that a blanket generalization can be made about neoplasms for example, when reported as secondary, do not involve greater resource use especially when CMS' own data analysis points to the exact opposite. Moreover, our understanding of the ICD-10 CM coding guidelines is that coders are only to add a secondary diagnosis to the encounter when the diagnosis would involve either clinical evaluation, treatment, diagnostic work, extension of the length of stay, or increased nursing or monitoring.

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As a result, ASTCT does not support the downgrading of the 767 neoplasm codes. We request CMS take a closer look at these codes as well as all of the codes it proposes changes for and provide an explanation about why its clinical advisors proceeded in recommending codes with significantly higher C1 values be downgraded. Additionally, our clinicians would be pleased to work with CMS to better understand its qualitative clinical rationale as well as its quantitative data methodology. We welcome the opportunity to engage in any manner CMS deems best, such as an open meeting, a separate rule-making process, or a Town Hall, for example.

Thank you for the opportunity to provide these comments on the FY 2020 IPPS proposed rule. 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,

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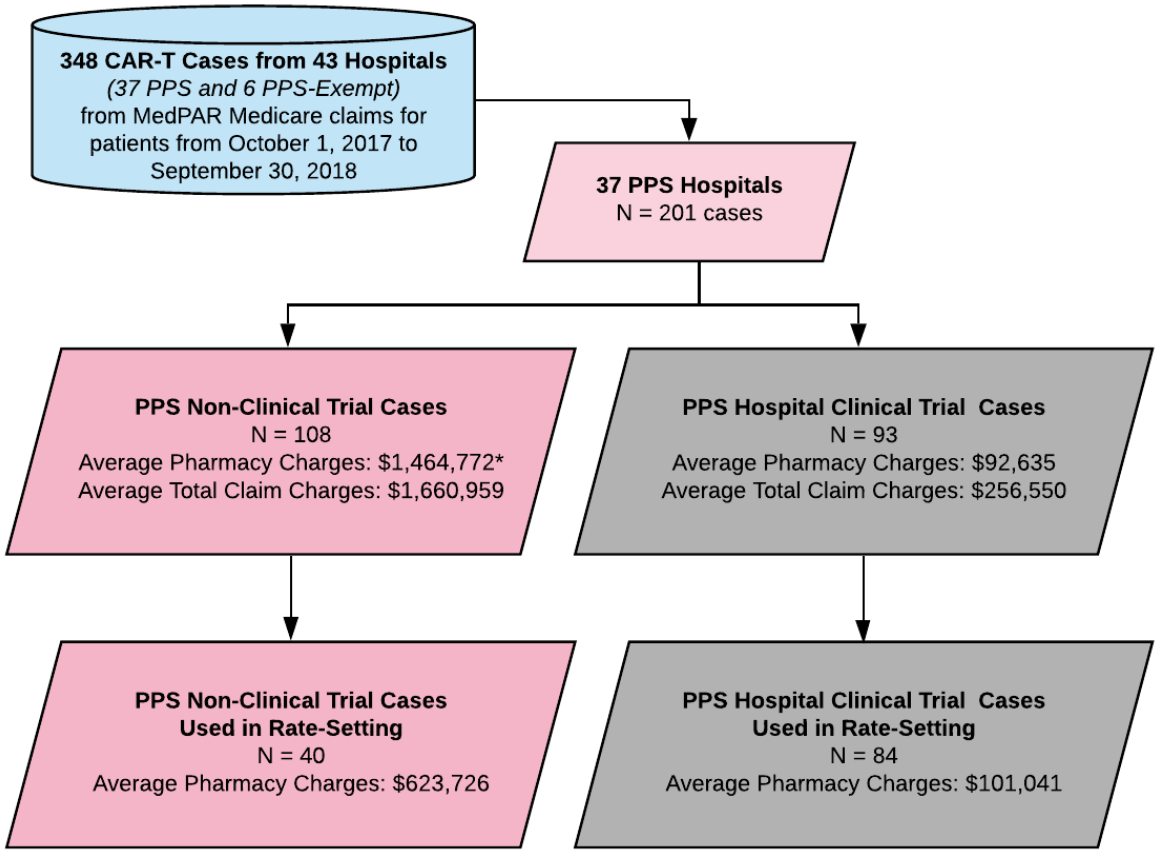
APPENDIX

A. BREAKDOWN OF PPS CENTER VOLUME



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B. PHARMACY CHARGE DATA

Non-Standardized Pharmacy Charges from Medicare's FY 2018 MedPAR Claims Data Released with the FY 2020 IPPS Proposed Rule					
State	Total Number of CAR-T Cases	CAR-T CLAIMS USED IN RATE-SETTING		CAR-T CLAIMS NOT USED IN RATE-SETTING	
		Non-Clinical Trial	Clinical Trial	Non-Clinical Trial	Clinical Trial
AL	*	$7,372	$36,524		
AZ	*			$1,268,376	
CA	*		$8,478		
CA	*	$1,641,085		$1,547,962	$1,256
CA	15	$1,078,560	$535,780	$1,102,317	
CA	*	$155,777	$34,983		
CO	*		$11,205		
CO	*	$13,255	$20,643		
GA	*	$8,484	$5,183	$32,041	
GA	*		$8,242		
IL	22	$29,818	$47,369	$2,111,318	
IL	*		$39,144		$47,212
KY	*		$284,098		
MD	*	$383,789	$21,665	$387,689	
MA	25	$1,675,013	$23,110	$1,609,480	$8,361
MA	*	$3,729	$7,831		
MA	27	$422,227	$3,744	$1,419,116	$19,862
MI	*			$2,289,023	
MN	*	$18,172			
MO	*	$1,330,024		$685,714	
NE	11		$17,743	$2,031,448	$20,065
NJ	*		$5,323		
NY	*		$21,615		
NY	*			$2,633,405	
NY	*	$1,334,905		$887,624	
NY	*	$797,296		$787,371	
NC	*		$7,212		
OH	*	$460,472	$109,038		
PA	*	$543,850	$13,149		
PA	14	$22,755	$59,589	$6,082,928	
TN	*	$1,054,290	$9,525		$5,853
TX	*		$706		
TX	*			$49,369	
UT	*		$33,637		
WA	*	$19,491			
WA	*			$115,016	
WI	*	$1,423,914	$28,146	$1,972,535	

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"*" = Numbers with counts of less than 11, or counts that could lead to a calculation of less than 11; all further breakdowns of the total number by clinical trial and non-clinical trial for volume would have met this criteria; therefore those breakdowns have not been shown

C. CHARGE DESCRIPTION MASTER SAMPLE

REVIEW OF PUBLICLY AVAILABLE CHARGE DESCRIPTION MASTER INFO FOR CAR-T PRODUCTS FROM A SAMPLE OF PPS HOSPITALS AS OF MAY 2019

State	Kymriah ALL Charge	Kymriah DLBCL Charge	Yescarta DLBCL Charge	Kymriah Single Charge
Alabama				$664,894
Arizona	$997,502	$783,302		
Arizona	$997,502	$783,302		
Arizona				$1,404,000
Arizona			$559,500	
California	$1,228,501	$1,018,495	$1,018,495	
California			$1,436,050	$1,828,750
California			$1,500,000	$1,900,000
California	$2,014,200	$2,014,200		
Colorado	$2,137,500	$167,850		$1,687,500
Connecticut	$2,137,500	$1,678,500		
Florida			$652,750	
Florida	$1,425,000			
Georgia	$950,000	$750,000		
Kansas	$395,380		$395,380	
Kentucky			$1,857,540	
Maryland	$4,750,000	$3,730,000	$3,730,000	
Massachusetts	$2,018,750	$1,585,250	$1,585,250	
Massachusetts				$1,000,000
Michigan	$546,250	$428,950	$474,456	
Minnesota			$466,250	
Missouri			$1,305,500	
Missouri				$570,000
New Jersey			$559,500	$712,500
New Jersey				
New York			$1,305,500	
New York			$1,305,500	
North Carolina			$637,084	$811,300
North Carolina			$2,275,300	$2,897,500
North Carolina			$1,125,026	
Ohio				$475,000
Oklahoma	$751,373			
Oregon	$712,500	$559,500	$559,500	
Pennsylvania			$447,600	$570,000
Pennsylvania	$6,900,000	$5,400,000	$5,400,000	
Pennsylvania				$554,167
Pennsylvania	$4,750,000	$3,730,000	$3,730,000	
Pennsylvania			$1,380,000	
Pennsylvania	$1,425,000	$1,119,000	$1,119,000	
Tennessee			$1,026,050	
Texas			$1,687,500	$1,687,500
Texas	$1,795,500	$1,409,940		
Texas	$804,435			
Utah			$1,250,000	$1,250,000
Virginia			$1,492,000	$1,900,000
Wisconsin			$746,058	$950,058
Wisconsin	$950,058		$746,058	

D. FY 2020 OPTIONS CONSIDERED BASED ON HOSPITAL A and HOSPITAL B

Hospital A Example Inpatient Hospital Claim			Hospital B Example Inpatient Hospital Claim		
Description	Units	Total Charges	Description	Units	Total Charges
Room & Board	14	$63,000	Room & Board	14	$63,000
Pharmacy	100	$45,000	Pharmacy	100	$45,000
Supplies	20	$13,000	Supplies	20	$13,000
Laboratory	520	$32,000	Laboratory	520	$32,000
All other	50	$75,000	All other	50	$75,000
CAR-T Drug*	1	$410,300	CAR-T Drug*	1	$1,492,000
Total Charges		$638,300	Total Charges		$1,720,000

** In the claims examples shown, the CAR-T product charge is split out from other pharmacy charges for illustrative purposes to demonstrate how reporting of the CAR-T product can occur. This would require explicit instructions from CMS.*

Hospital and Patient Characteristics

Both Hospitals A and B:

- **Are certified to provide CAR-T therapy**
- **Pay the manufacturer $373,000**
- **Have a wage-index of 1.0 and no other adjustments**
- **Have an overall operating cost-to-charge ratio of 0.25**
- **Treat the same type of patient**

The only difference between Hospital A and B is the CAR-T product charge billed on the claim because Hospital B's charges are reflective of its operating CCR of .25, but Hospital A's are not.

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		Options for FY 2020					
	FY 2019	CMS' proposal of changing NTAP cap from 50% to 65%	CMS' proposal of changing NTAP cap from 50% to 80%	COMBO Proposal: CMS' proposal of changing the NTAP cap from 50% to 65% AND adds in the use of actual product acquisition cost as a way to effectuate the "CCR of 1.0" concept in the NTAP and outlier formula	**COMBO PROPOSAL: Starts with CMS' proposal of changing the NTAP cap (we model 80%) AND adds in the use of actual product acquisition cost as a way to effectuate the "CCR of 1.0" concept in the NTAP and outlier formula**	FY 2020 - CMS Request for Comments on Uniform NTAP at 65% for CAR-T Only	FY 2020 - Improvement Upon CMS' Request for Comments on Uniform NTAP for CAR-T Only from 65% to 80%
Options [1]	**Current**	**Option 1**	**Option 2**	**Option 3**	**Option 4**	**Option 5**	**Option 6**
MS-DRG[2]	016	016	016	016	016	016	016
NTAP	Current methodology	Update to the percentage cap used in the current formula	Larger update to the percentage cap used in the current formula	Update to the percentage cap used in the current formula & then exclude the CAR-T product charge from total charges, reduce remaining charges to cost, then add back $373,000 for CAR-T product cost (or using data in the value code field) and then apply the usual formula	Larger update to the percentage cap used in the current formula & then exclude the CAR-T product charge from total charges, reduce remaining charges to cost, then add back $373,000 for CAR-T product cost (or using data in the value code field) and then apply the usual formula	Change formula to 65% of NTAP as uniform payment	Change formula to 80% of NTAP as uniform payment
Outlier	Current methodology	Current methodology		Exclude the CAR-T product charge from total charges, reduce remaining charges to cost, then add back $373,000 for CAR-T product (or using data in the value code field) plus MS-DRG payment plus outlier threshold cost and apply the usual formula		Current methodology	
Financial Impact Based on Hospital A w/ 10% Mark up	($303,003)	($300,216)	($297,503)	($50,607)	($39,417)	($145,057)	($89,107)
Financial Impact Based on Hospital B w/ 400% Mark up	($61,325)	($50,607)	($39,417)	($50,607)	($39,417)	($50,607)	($39,417)
Notes:							
(1) Each option is based on the sample claims provided							
(2) MS-DRG payment based on the assumption that both hospitals have a wage index of 1.0 and no adjustments for IME or DSH in order to isolate issues of charge compression.							
(3) Financial impact to individual hospitals will vary based on hospital's charging practices, hospital's own operating cost-to-charge ratio, wage index, IME and/or DSH adjustments, amount of outlier received (we used a simple formula and did not compute capital and operating separately), and most importantly actual patient care costs (i.e., patients with complications requiring additional drugs, therapies, intensive care, etc. will be more costly than our simple example) of the case.							

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