

November 1, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Options for CAR-T Inpatient Payment for FY 2021

Dear Administrator Verma:

The American Society for Transplantation and Cellular Therapy (ASTCT) and the American Society of Hematology (ASH) appreciate the Centers for Medicare and Medicaid Services' (CMS) continued engagement with our Societies regarding Chimeric Antigen Receptor T-cell (CAR-T) therapy. We are writing to request that CMS maintain the New Technology Add-on Payment (NTAP) for FY 2021 in order to ensure when CMS creates a new MS-DRG for CAR-T it is based on the best data available. Unfortunately, we do not believe this data is what the agency has already collected for FY 2021 rate-setting.

The ASTCT is a professional membership association of more than 2,200 physicians, scientists, and other healthcare 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 Food and Drug Administration (FDA) approvals for CAR-T therapy.

ASH represents more than 17,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

Our Societies fundamentally see cellular and gene therapies as a new branch of medicine, one that CMS' current Inpatient Prospective Payment System (IPPS) could never have anticipated. We recognize CAR-T therapy is the first from this class that requires CMS to balance protecting patient access to this new class of therapies with responsible stewardship of the Medicare trust fund as it engages in rate-setting. Therefore, CMS must take the time necessary to ensure the appropriate

balance is struck in rate-setting for CAR-T therapy rather than risk setting a rate that will stifle innovation of future CARs and other cellular and gene therapies.

ASTCT and ASH respectfully request that CMS maintain the NTAP for the FDA-approved CAR-T products for FY 2021 and delay creating a new MS-DRG until FY 2022. We believe this is the only policy that will maintain patient access to this therapy in the short term while allowing CMS to carefully consider how to develop an equitable MS-DRG for CAR-T that will set a precedent for future cellular therapies.

The NTAP for CAR-T has only been available for two fiscal years, yet CMS recognizes a service as new for two or three years. We ask that CMS provide the NTAP payment for the two FDA-approved CAR-T products for a third year and use this time to collect better data for rate-setting. In this letter, we detail the deficiencies in the data currently available and why we are confident the data available for FY 2022 rate-setting will be substantially improved. Ultimately, we believe CMS, patients, and providers will benefit from this extension that allows the Agency to take the time to collect accurate data and evaluate if and how its IPPS mechanisms should be modified to address this new and unique branch of medicine. We also outline specific methodologies for CMS to consider when developing a new MS-DRG for CAR-T that will improve access to transformative therapies by Medicare beneficiaries' long term. Please find the summary of our recommendations below; detailed discussions of these individual item are included in the following pages.

Summary of Recommendations for FY 2021

- Maintain NTAP for CAR-T through FY 2021;
- If NTAP is not maintained:
 - Create a new MS-DRG for T-cell immunotherapy using only FY 2019 CAR-T claims with no clinical trial Z00.6 diagnosis code and with pharmacy charges greater than \$373,000; and
 - Use a pharmacy off-set similar to CMS' existing device off-set mechanism to pay for the T-cell immunotherapy MS-DRG for CAR-T claims where the hospital receives the cell therapy product at no cost and reports only a token charge in revenue code 0891 which is for special processed drugs – FDA approved cell therapy;
- Release detailed sub-regulatory guidance on coding, billing, and appropriate charging including requiring value code 86 on claims which according to NUBC is for the reporting of invoice/acquisition cost of modified biologics for use with revenue category 089x so that actual product acquisition cost data can be collected by CMS.

Background

Our Societies remain committed to finding solutions for the challenges posed by the current payment system issues to provide equitable reimbursement for these unique and innovative treatments. We have provided detailed feedback to CMS on payment solutions for CAR-T since 2017 and most recently on its proposals during this year's IPPS rulemaking cycle. While we recognize the agency took a significant step forward by increasing the New Technology Add-on Payment (NTAP) cap from 50 to 65% in FY 2020, we remain concerned with the total reimbursement for inpatient administration of CAR-T for several reasons. First, there are multiple billing scenarios that may result in the use of inappropriate claims being utilized in rate-setting, including traditional clinical trial cases, and when hospitals receive cell therapy products at zero cost due to manufacturing issues. Also, not all CAR-T providers are receiving the maximum NTAP payment due to concerns about applying the mark-up necessary to trigger full NTAP payment, which is typically a dollar charge in excess of \$1.5 million.

We recognize it is not CMS' concern should providers not avail themselves to the full NTAP while it is available, but it becomes a problem if CMS uses claims data from these providers for future rate-setting which will negatively impact providers that have been charging appropriately and receiving their full NTAP.

The Societies were pleased to see that CMS broadened the coverage policy in its final National Coverage Decision (NCD) for CAR-T therapy consistent with our recommendations. However, we remain deeply concerned that a broad coverage policy and poor reimbursement puts institutions in a difficult position of being required to provide this therapy while being inadequately reimbursed to cover the costs associated with it. This policy may further limit patient access to this important therapy and other cellular immunotherapies that will quickly follow CAR-T if institutions decide not to offer cellular therapy programs. Medicare reimbursement that fails to cover the product acquisition cost is unsustainable for centers, and there are centers that have already chosen not to offer CAR-T to patients for this reason. Unlike other services, centers have not been able to subsidize Medicare patients with margins from patients with private insurance. On average, the private plans are reimbursing only enough to cover the product acquisition cost, leaving a shortfall on the cost of care. There is no offset of expenses as CMS usually expects with new therapies such as this because of the high acquisition cost.

Again, we are grateful to CMS leadership for their continued engagement with us on CAR-T coding, billing, coverage, and payment policy issues. During our most recent meeting with the Hospital and Ambulatory Policy Group on July 24, 2019, our Societies were able to share our initial ideas about payment options for CAR-T after the NTAP's expiration. We are pleased the Agency continues to solicit our feedback and we make our recommendations for FY 2021 below.

Recommendations

I. CMS Should Maintain the CAR-T NTAP in FY 2021

Given the uniqueness of CAR-T as a personalized cellular immunotherapy, the ASTCT and ASH fundamentally believe the most appropriate reimbursement solution for FY 2021 is maintaining the NTAP for an allowed third year for the two FDA-approved CAR-T products with cases continuing to group into MS-DRG 016. There is a confluence of unusual factors relating to CAR-T therapy that support this recommendation: unusually high prices, lack of discounts due to the personalized nature of the therapy, minimal data reflecting use of the commercial products for future rate-setting, and continued provider concerns about applying mark-ups to maximize the NTAP dollars available given the concerns around price transparency.

Our recommendation is supported by 42 CFR §412.87(b)(2) which provides the following:

A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the [inpatient hospital](#) code (as defined in section 1886(d)(5)(K)(iii) of the [Social Security Act](#)) assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered “new” under the criterion of this section.

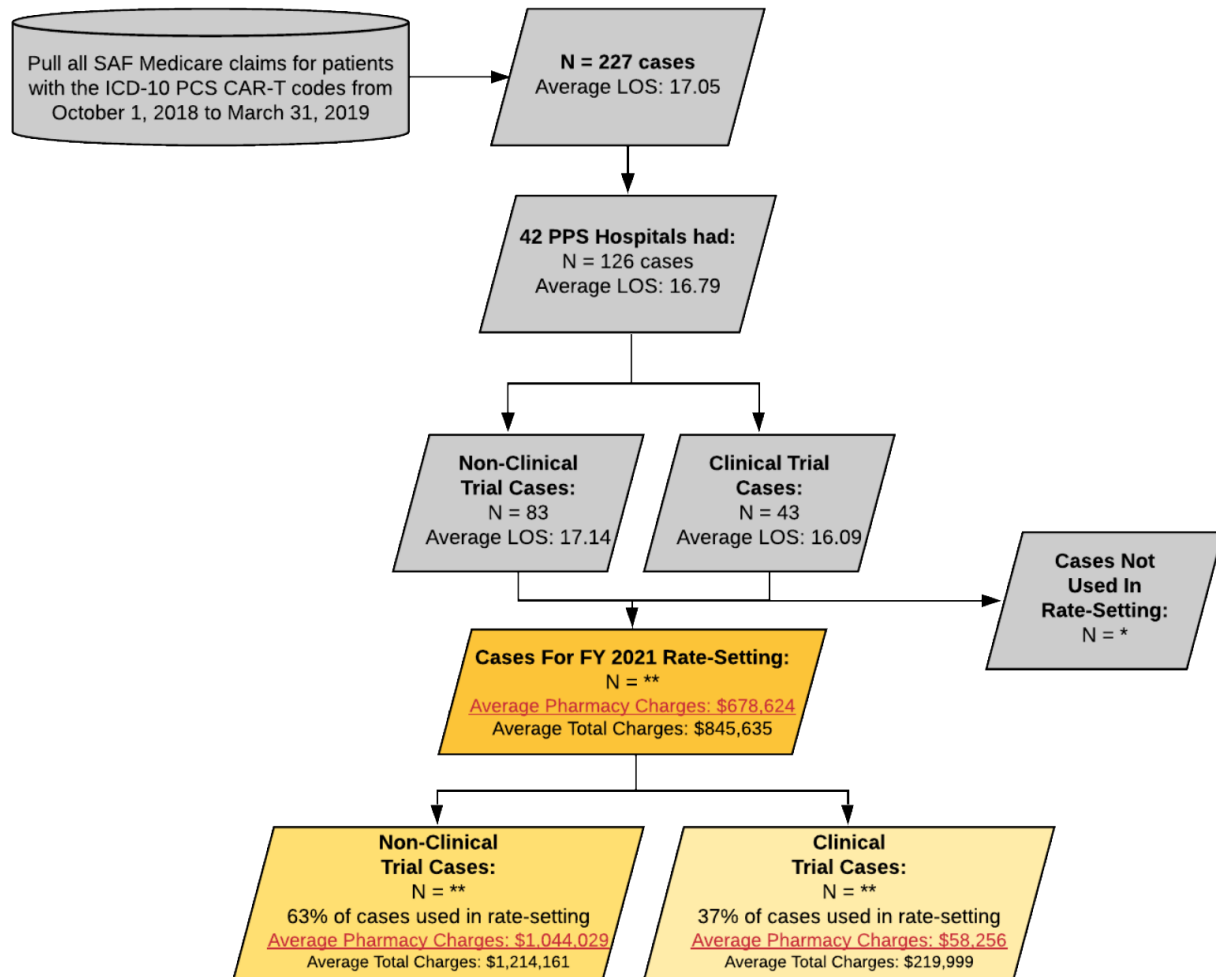
We recognize that data for CAR-T therapy first became available in FY 2018. However, the volumes in FY 2018 were very low and no NTAP assignment was approved during that first fiscal year given the products’ approval timing. The NTAP has only been in place for FY 2019 and FY 2020. The Societies urge CMS to use its authority to maintain the NTAP for a third year to use more robust FY 2020 data (i.e., presence of revenue code 891 to isolate product charges) when setting a relative weight for a new T-cell immunotherapy MS-DRG which could be introduced starting October 1, 2021.

We remain concerned that CAR-T therapy has been underutilized with Medicare beneficiaries, as evidenced by claims data reports of less than half and perhaps closer to only a quarter of the estimates made initially by the manufacturers. This data is supported by the reports from our member clinicians, who state that due to the financial considerations, many centers are reluctant to use commercial CAR-T products, despite robust data demonstrating their clinical benefits. CMS must carefully consider how it will create a new MS-DRG for this therapy and strike the appropriate balance between maintaining usual rate-setting methodology, while recognizing that providing fair and equitable payment will help ensure that providers can afford to provide access to patients.

Based on our analysis, almost half of the inpatient cases in the FY 2018 MedPAR data and about one-third of the cases from the first two quarters of FY 2019 SAF data are clinical trial cases based on coded information reported on the claims. In addition to these specifically coded cases, there

are many more that appear to be trial cases as evidenced by the reporting of very low pharmacy charges. These cases may be the result of simple coding mistakes, such as leaving off the clinical trials Z00.6 diagnosis code from the claim, or they may be reflective of a broader problem of how to report claims for CAR-T therapy when manufacturing issues have resulted in an out-of-specification product (i.e., does not meet FDA labeling) being provided by the manufacturer at no cost to the provider under an expanded access protocol (EAP). Some of these erroneous claims will likely be trimmed out during CMS' normal rate-setting process, but others will remain. The remaining cases will not have charges that are representative of true non-clinical trial or what we call "commercial cases," since the product cost, the largest portion of the total case cost, will be missing.

The figure below provides a breakdown of what we are seeing from the first two quarters of FY 2019 SAF data as described above.



* = Count of less than 11

** = Greater than 11 but displaying number could lead to a calculation of a count less than 11

If CMS were to maintain NTAP for a third year and release guidance to providers on appropriate claims submission, including an immediate instruction to resubmit incorrectly coded or billed claims, there would be far more accurate data – and more total cases – available to develop a new T-cell immunotherapy MS-DRG. For example, this guidance could instruct providers that had not previously adopted the use of revenue code 0891 starting April 1, 2019 to correct and resubmit their claims. The guidance should also instruct hospitals on how to report EAP cases to CMS, including but not limited to the use of a token charge in revenue code 0891 to indicate the cellular therapy product was received at no cost.

We expect to see more clinical trial cases than is typical for established MS-DRGs and anticipate this will continue for the foreseeable future based on the current pipeline. Therefore, we believe the Agency would benefit from having one more year of data to evaluate this trend, the impact clinical trial cases would have on the creation of a new T-cell immunotherapy MS-DRG, and how to properly address these cases in rate-setting.

As CMS is aware, the ASTCT anticipated challenges with usual rate-setting for CAR-T cases as early as 2017, when we first offered payment options to the Agency for consideration. The Societies requested CPT codes from the American Medical Association to assist CMS with these processes and to begin to address the limited visibility CAR-T has in claims data. We also pursued unique revenue codes with the National Uniform Billing Committee (NUBC) to isolate the engineered cellular therapy product charge and the CAR-T services (cell collection and cell processing) on hospital claims. We requested the creation of a unique value code so that hospitals could report their actual acquisition cost for their cell therapy product to CMS on claims. We have worked extensively to provide education to the provider community on appropriate coding, billing, and charging practices including an explanation of how CMS' NTAP formula works. Finally, we requested additional sub-regulatory guidance so that providers would be fully informed and timely in their use of the newly created revenue codes as of April 1, 2019. We have asked CMS to require the reporting of value code 86 and continue to encourage CMS to ask its reporting to be mandatory so that the Agency can better understand actual acquisition costs from claims data to utilize it appropriately in future rate-setting.

Coding and billing system changes are critically important, but they take time to achieve; each change had a different implementation date and varying adoption timeframes by the certified CAR-T centers. Given the two-year time lag on the data CMS uses for future rate-setting, it was impossible for much of the data currently in CMS's historical claims to be reflective of the types of data elements mentioned above. We ask that CMS consider this necessary lag in the possibility of reporting clear and useful data be considered as another compelling reason for CMS to extend the NTAP designation. Based on these extenuating circumstances, **the Societies respectfully request that CMS continue to provide the NTAP for CAR-T in FY 2021 and defer the development of a new MS-DRG for CAR-T until FY 2022.**

II. Creating a New T-Cell Immunotherapy MS-DRG

As discussed, the Societies strongly recommend that CMS delay the development of an appropriately paying MS-DRG for CAR-T, which properly factors in the cost of the cell therapy product until FY 2022. However, we wish to provide recommendations on rate-setting should CMS reject this recommendation. As CMS recognizes in the FY 2020 IPPS rulemaking, there are a number of factors that should be considered when developing a new MS-DRG for CAR-T which would not apply when developing a new MS-DRG for other services.

Given our significant concerns about the FY 2019 claims data available for FY 2021 rate-setting, we urge CMS to depart from its usual processes in developing the relative weight for this new MS-DRG in order to account for both the high volume of CAR-T clinical trial cases and the high variability of pharmacy charges found in the data if CMS will not maintain the NTAP. To ensure appropriate patient access, it is critical for CMS to develop the relative weight for a new T-cell immunotherapy MS-DRG so that program hospitals receive fair and equitable reimbursement.

Our Societies believe when CMS sets the rate for a new T-cell immunotherapy MS-DRG it must be done with the following three goals in mind:

- A new MS-DRG for T-cell immunotherapy should result in **fair and equitable payment** to providers by avoiding systematic under-payment of commercial cases and systematic over-payment of clinical trial cases to preserve beneficiary access to care, while maintaining program integrity and continuing to support innovation in this new branch of medicine.
- The creation of an appropriately paying new MS-DRG for T-cell immunotherapy must **properly pay for clinical trial cases** that exist as a high proportion of total CAR-T cases in the data.
- The creation of an appropriately paying new MS-DRG for T-cell immunotherapy must **address high pharmacy charge variability** in the claims data.

A. Rationale for Creating a New T-Cell Immunotherapy MS-DRG

The current FY 2020 national IPPS payment rate for MS-DRG 016 (Autologous Bone Marrow Transplant or T-cell Immunotherapy), into which CAR-T cases are currently grouped, is approximately \$43,000. Once NTAP expires (ideally at the end of FY 2021 as requested above) CMS can choose to treat CAR-T cases in the following ways; it could keep them in MS-DRG 016, create a new MS-DRG for T-cell immunotherapy, or implement an alternative mechanism to avoid systematically underpaying providers for this therapy potentially further limiting patient access.

Using the first two quarters of FY 2019 SAF data, CMS' usual trimming methodology, and the current FY 2020 national base payment amount for an MS-DRG results in a national payment rate

of approximately \$47,000. Even with the usual application of adjustments (i.e., wage index, IME, and DSH) and the availability of the outlier mechanism providers will not be adequately reimbursed for CAR-T. Outlier payments are not likely to make up for an inadequate base MS-DRG payment nor do we believe the outlier payment methodology should be systematically relied upon to make up for an inadequate base MS-DRG payment. Rather, the outlier pool should remain available to address extraordinary patient care costs across the IPPS system should they arise.

Equally material to this discussion is that if CMS keeps CAR-T cases in MS-DRG 016, it will not preserve clinical or resource homogeneity - typically held as fundamental principles of the MS-DRG classification system used for inpatient payment. This is clearly evidenced by an analysis we conducted using the FY 2018 Proposed Rule MedPAR data shown in Table 1 below. We isolated drug charges as a percentage of total charges for only autologous bone marrow transplant cases in MS-DRG 016 and compared those to pharmacy charges as a percentage of total charges for all CAR-T cases when placed in their own MS-DRG, versus pharmacy charges as a percentage of total charges for only commercial CAR-T cases when placed in their own MS-DRG. We also examined the standardized costs.

A replication of MS-DRG 016 for FY 2020 in Table 1 below (that includes both stem cell transplant and CAR-T cases) shows that drug charges are approximately 44% of the total case charges, and a third of the total case costs. This pattern would bear out in a simulation of MS-DRG 016 that has no CAR-T cases: drug charges would be estimated at 42% of the total case charges and 32% of the costs. This is in marked contrast to a simulated new CAR-T only MS-DRG, where drug charges are near 80% of the total case charges, and almost three quarters of the total case costs. And when we isolate our simulation of a new CAR-T MS-DRG to only those cases with no clinical trial Z00.6 diagnosis code (i.e., commercial cases) we see an even higher proportion of drug charges and costs compared to overall case charges and case costs, at nearly 88% and 83%, respectively. These are enormous differences that showcase the huge impact the cell therapy product has on overall case charges and costs and demonstrates how different the resource use for CAR-T is compared to the vast majority of autologous transplant cases in MS-DRG 016. These findings are not at all surprising given the known cost of the product for DLBCL to providers is \$373,000.

Table 1: Comparison of Drug Charges and Costs as a Percent of Total in MS-DRG 016 vs. Variations of a New T-cell Immunotherapy or CAR-T MS-DRG for FY 2020 Using FY 2018 Proposed Rule MedPAR Data

MS-DRG Type and Number	DRG Title	Charges			Cost (standardized)		
		Total Charges	Drug Charges	Drug charges as a % of total case charges	Total Cost	Drug Costs	Drug costs as a % of total case cost
Replication of MS-DRG 016 for FY 2020 inclusive of stem cell transplant and CAR-T cases							
016	AUTOLOGOUS BONE MARROW TRANSPLANT W CC/MCC OR T-CELL IMMUNOTHERAPY	\$248,188	\$108,931	43.9%	\$46,854	\$15,596	33.3%
Creation of a new CAR-T MS-DRG with all CAR-T cases but no stem cell transplant cases							
NEW	New CAR-T DRG	\$863,089	\$682,325	79.1%	\$117,560	\$85,426	72.7%
016	AUTOLOGOUS BONE MARROW TRANSPLANT W CC/MCC OR T-CELL IMMUNOTHERAPY	\$236,117	\$99,440	42.1%	\$45,766	\$14,597	31.9%
Creation of a new CAR-T MS-DRG with no clinical trial CAR-T cases and no stem cell transplant cases							
NEW	New CAR-T DRG, No Clinical Trials	\$1,522,842	\$1,333,364	87.6%	\$204,776	\$170,229	83.1%
016	AUTOLOGOUS BONE MARROW TRANSPLANT W CC/MCC OR T-CELL IMMUNOTHERAPY	\$236,117	\$99,440	42.1%	\$45,766	\$14,597	31.9%

We expect this same pattern to persist in the FY 2019 data, as well as future years, given CAR-T and other cellular therapies are on the market and will soon receive FDA approval. Therefore, it would be consistent with CMS' general authority under sections 1886(d)(4)(B) and (C) of the Social Security Act to create a new MS-DRG rather than continuing to assign CAR-T cases into MS-DRG 016 once the NTAP for CAR-T expires. This will allow CMS to assign and update appropriate weighting factors in a manner that reflects the resources involved with immune effector cell therapy which involves a new technology that impacts the relative use of hospital resources (as stated under paragraph 1886(d)(5)(K)).

B. Rationale for Departing from Usual Rate-Setting in Creating an Appropriate Relative Weight for FY 2021 if CMS does not maintain the NTAP

Developing an appropriately paying new T-cell immunotherapy MS-DRG will require CMS to grapple with the dual issues of 1) having a very large percentage of clinical trial cases making up

the MS-DRG total case volume and 2) a clinical care episode in which the new technology's cost constitutes an extreme proportion of the total case cost. We do not see record of CMS ever addressing these issues simultaneously. We recognize that CMS' usual rate-setting methodology would require the agency to utilize all CAR-T claims regardless of whether they are clinical trial or not, regardless of whether the data is grossly and obviously incorrect, and regardless of whether its' own trimming logic removes correctly coded claims while allowing aberrant claims to remain. We worry that the averaging process that CMS relies on only holds true when there is a sufficiently large volume of claims, which is not at all the case with respect to CAR-T volume.

If CMS were to use its usual rate-setting methodology by keeping all CAR-T cases and applying its usual trimming logic, the result will be a new T-cell immunotherapy MS-DRG that systematically underpays providers for their commercial CAR-T cases. We simulated what the FY 2021 payment rate for a new T-cell immunotherapy MS-DRG would be using all CAR-T cases from the first two quarters of FY 2019 SAF data and CMS' usual rate-setting methodology, including trimming, and the result is a national unadjusted payment of approximately \$131,000 (based on FY 2020 standardized national payment from the final rule correction notice) excluding possible outlier payment.

For some proportion of providers, this will result in a significant under-payment given that each provider is required to pay \$373,000 for acquisition of the drug for DLBCL before providing any additional clinical services. This significant underpayment does not represent fair and equitable payment, nor would it be consistent with CMS' general authority under sections 1886(d)(4)(B) and (C) of the Social Security Act.

For this reason, we ask CMS to make some minor adjustments to its usual rate-setting methodology which we believe is again consistent with CMS' general authority under sections 1886(d)(4)(B) and (C) of the Social Security Act to create a new MS-DRG that allows CMS to assign and update appropriate weighting factors in a manner that reflects the resources involved with immune effector cell therapy, including drug acquisition costs. Given the large number of therapies in the pipeline, we believe it is absolutely critical for CMS to act now, at the outset, to establish an appropriately paying T-cell immunotherapy MS-DRG so that the clinicians and hospitals on the cutting edge of this treatment are able to continue treating patients regardless of the NTAP status of a product.

C. Options for FY 2021 Rate-Setting

Departing from usual rate-setting as stated above will be necessary if CMS proceeds with creating a new MS-DRG for T-cell immunotherapy for FY 2021 so that it is able to account for the large number of clinical trial cases present in the data as well as the large variation in pharmacy charges. This is one key reason why we urge CMS to maintain the NTAP in FY 2021 rather than proceeding with the creation of a new MS-DRG. In addition to this, we recognize that the options outlined below will necessitate CMS to determine the best, most appropriate mechanism to pay for future

T-cell immunotherapy cases where there is no cell therapy product cost incurred by the hospital, either because of new therapies in clinical trials or due to continued manufacturing issues resulting in providers receiving cell therapy products at no cost. Below are the primary options the ASTCT has identified to date for how CMS could develop an appropriate payment rate for the new T-cell immunotherapy MS-DRG, however **we strongly recommend CMS adopt option 2 only if CMS does not maintain the NTAP in FY 2021.**

Option 1: Commercial Cases – develop the relative weight for the new T-cell immunotherapy MS-DRG using only CAR-T “commercial” cases. For the purposes of our simulations using both MedPAR and SAF data we defined these cases as ones that do not have the clinical trial Z00.6 diagnosis code present¹. While this seems reasonable, our primary concern is that there are a number of claims in the first two quarters of the FY 2019 SAF data (as there were in the FY 2018 MedPAR data) that do not have the clinical trial Z00.6 diagnosis code, yet the reported pharmacy charges are **so low** that they signal the case is likely a clinical trial or a case in which the provider received the cell therapy product under an EAP and did not know how to report it. We calculated the FY 2021 payment rate for a new T-cell immunotherapy MS-DRG would be approximately \$183,000 using this methodology. We do not believe this is an appropriate payment rate for a new T-cell immunotherapy MS-DRG, nor do we believe it would be appropriate for CMS to utilize a methodology that only removes what is coded as clinical trial cases with the Z00.6 diagnosis code without any consideration of the unusually low pharmacy charges present on many other cases that are missing the Z00.6 diagnosis code as we consider these claim charges to be highly questionable.

Option 2: Commercial Cases with a Minimum Reported Pharmacy Charge – develop the relative weight for the new T-cell immunotherapy MS-DRG using only CAR-T “commercial” cases with a pharmacy charge greater than \$373,000. We define these cases as ones that do not have the clinical trial diagnosis code Z00.6 as in the above simulation but in this simulation we also require that the case **does have** pharmacy billed charges that are at least equal to or greater than the known cost of the drug for the adult DLBCL indication (that the provider paid the manufacturer \$373,000). This option eliminates claims with what we consider unusually low pharmacy charges, as discussed as a concern under Option 1, and allows for what can be considered the bare minimum pharmacy charge to allow in the rate-setting process since even this minimum charge of \$373,000 is likely aberrant for a commercial CAR-T case given CMS’ rate-setting methodology will multiply this value by the national pharmacy cost center of 0.19 resulting in a pharmacy cost estimate of \$70,870. This type of computed cost is so far below the actual invoice amount that providers pay to the manufacturer for the cell therapy product that one could reasonably argue that the bare minimum pharmacy charge should easily be a multiple of \$373,000 and still would not result in an accurate estimation of the CAR-T product cost let alone accounting for other drug costs associated with the inpatient stay. For example, even billed pharmacy charges of \$746,000 (double the acquisition cost) can be considered incorrect because when this is multiplied by the national pharmacy cost center of .19 the computed cost is \$141,740; again, well below just the product

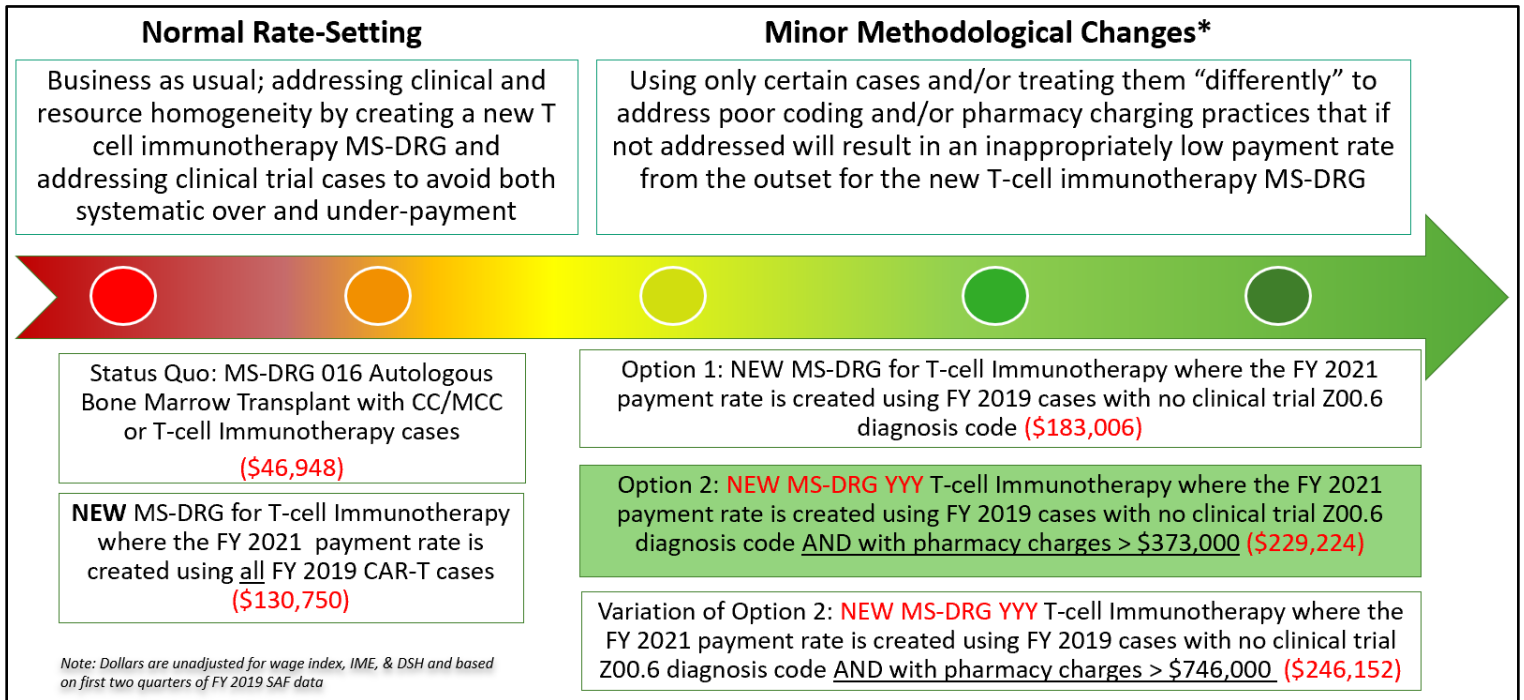
¹ We only used the diagnosis code since the MedPAR data CMS releases for analysis does not contain condition code 30. We recognize CMS in its analysis could use both claim data elements.

acquisition cost. We simulated what the FY 2021 payment rate for a new T-cell immunotherapy MS-DRG would be according to the methodology described here using the first two quarters of FY 2019 SAF claims and a bare minimum pharmacy charge of \$373,000 and the result is a national payment of approximately \$229,000.

We recognize that any request to depart from regular rate-setting is challenging and should not be made lightly. This is why we only discuss options around excluding cases with pharmacy *charges* below, at a level most could reasonably agree is the bare minimum litmus test that can be applied in evaluating cases for inclusion in rate-setting, rather than proposing additional alternatives that would involve CMS removing cases with pharmacy charges that when reduced to costs fall below a certain threshold, such as \$373,000. We believe it is reasonable for CMS to evaluate billed pharmacy charges and remove grossly erroneous ones; even in these cases as our simulations show, the resulting pharmacy cost does not reflect the actual acquisition cost of the CAR-T products. That is why, in order to meet the objective of avoiding underpayment, while not making too great a departure from normal rate-setting, **we advocate for the selection of Option 2**. This option allows conservative removal of incorrectly reported claims and creates a relative weight from the outset for a new T-cell immunotherapy MS-DRG using the bare minimum of what would reasonably be considered a correctly coded and charged claim.

We would expect CMS to use this methodology as a temporary measure for one year but not more than two years so that it has at least one full year of cell therapy charges reported in revenue code 0891, and ideally more accurately reported claims from providers as a result of the additional sub-regulatory guidance the agency would release.

The graphic below summarizes the various options we believe CMS has available for FY 2021 rate-setting, with our preferred Option 2 highlighted in green. We would be pleased to discuss our thinking around the aforementioned options along with others that we evaluated and discarded for FY 2021 but that may be useful for future years. We will be requesting a follow up meeting with the Agency in the coming weeks.



The above options outlined how CMS could create the relative weight for the new MS-DRG using FY 2019 claims data for FY 2021 payment of commercial CAR-T claims due to the claims included in the rate-setting process which means CMS will still have to address how to identify and appropriately pay for CAR-T cases in FY 2021 for which a provider does not incur a cell therapy product cost. We believe CMS has some options on how to handle this and we discuss this below.

III. Making Appropriate Payments Starting in FY 2021

A. Identifying T-cell immunotherapy Cases Starting in FY 2021 for which the Provider Did Not Incur a Cell Therapy Product Charge

The Societies used the presence of the diagnosis code Z00.6 to identify clinical trial claims in both the FY 2018 MedPAR data and the first two quarters of FY 2019 SAF data because this was our only option. However, we believe there is a better option to identify clinical trial cases in the future.

Beginning with the FY 2021 payment year, CMS should not use clinical trial claim indicators alone to identify whether or not a provider incurred an acquisition cost for cell therapy products as it could inadvertently pay providers inappropriately. Specifically, the Agency should be aware that it is possible to have the clinical trial diagnosis code Z00.6 and condition code 30 on a claim for a patient receiving commercial CAR-T because the item or service under study/trial is another drug

(reported through a pharmacy revenue code such as 25x and not through revenue code 0891) to help mitigate complications of CAR-T. Because these cases will exist, for FY 2021 and beyond, CMS should have HIPAA transaction set compliant claims from providers reflecting the recently implemented NUBC revenue code 0891 for cell therapy products.

If the hospital does not incur an acquisition cost for the cell therapy product, it would still need to report revenue code 0891 to indicate the product was given, but the billed charge would reflect only a token amount which CMS should clarify through sub-regulatory guidance so providers know how to report. CMS could use both the presence of revenue code 0891 with a token charge and the clinical trial claims indicators and/or require the use of value code 86 to truly isolate claims for which the provider did not incur a cell therapy product cost if it likes, but we believe the simplest check is to use revenue code 0891 and a token charge.

B. Paying Appropriately for T-cell immunotherapy cases starting in FY 2021 for which the Provider Did Not Incur a Cell Therapy Product Charge

While there are several ways for CMS to pay appropriately for claims with no cell therapy product cost, the ASTCT's preferred option is to apply an offset to the MS-DRG payment in these cases not unlike CMS' use of a device off-set to ensure the MS-DRG payment will not result in an overpayment to the provider. The offset can only be effectively used if CMS adopts the recommendations outlined above for setting a new MS-DRG weight.

The offset can be the average CAR-T product expense included in the MS-DRG payment. The offset we are recommending here is conceptually similar to that CMS uses for device-dependent MS-DRGs with the exception that the offset that would be applied to the new T-cell immunotherapy MS-DRG. CMS would need to calculate the average CAR-T product cost imbedded in the MS-DRG and use this amount to offset a CAR-T MS-DRG payment where the 0891 charge is a token charge. This is slightly different than the reported value of the free/credit device/drug as reported by the provider on the claim using the value code field. CMS would apply the CMS determined CAR-T product offset when the hospital reports a token charge in revenue code 0891 because the token charge indicates the provider did not incur an acquisition cost for the CAR-T product. We believe this option most closely adheres to current IPPS system processing and as a result, we surmise it to be a relatively simple option for CMS to implement that would result in appropriate payment for all CAR-T cases.

IV. Release Sub-Regulatory Guidance As Soon As Possible

The Societies urges CMS to release sub-regulatory guidance on the following to hospitals as soon as possible to ensure complete and accurate claims data are submitted by providers:

- a. Hospitals must report HIPAA-transaction set compliant claims by using revenue code 0891 to report their cell therapy product charge. This revenue code must be used

- regardless of whether the hospital incurred a cost for the cell therapy product. In cases where the hospital does not incur a cost, a token charge must be reported. This instruction will enable CMS to examine claims that have a token charge but that may be missing the clinical trials diagnosis coded Z00.6 and condition code 30 and still know to apply the cell therapy drug off-set so that cases are not overpaid. Similarly, if CMS does see clinical trials diagnosis code Z00.6 and condition code 30 but does not see a token charge reported, then it will know to make the regular payment associated with the new T-cell immunotherapy MS-DRG since the item under study would not be the cell therapy product.
- b. Require hospitals to report Value Code 86 and the actual dollar amount they paid to acquire the cell therapy product. This taken together with the charges reported in Revenue Code 0891 will provide CMS with additional information about whether to apply the cell therapy product off-set or not.
 - c. Create a new, distinct pharmacy standard cost center for cell and gene therapy products on the hospital cost report. Some hospitals have already set up their own subscribed lines but having CMS issue guidance that requires a separate line would ensure more accurate reporting to monitor and address concerns with charge compression going forward.

Summary

The Societies strongly believe in preserving patient access to the transformative cell therapies that are already on the market, and promoting the innovation of new ones, all while maintaining the integrity of the IPPS system. We also recognize it is a complex undertaking, if CMS were to depart from its usual rate-setting process. Therefore, we recommend CMS maintain the NTAP for FY 2021 in order to have the best data possible to set a new MS-DRG in FY 2022. If that is not possible, we believe our preferred option of CMS creating a new T-cell immunotherapy MS-DRG using only CAR-T claims with pharmacy charges greater than \$373,000 (the known product cost) as a temporary measure will allow the Agency to set the most appropriate MS-DRG relative weight at the outset for the current two T-cell immunotherapies.

In the future, CMS will need not limit its use of CAR-T claims in this manner, as we expect providers to become more proficient in accurately reporting their CAR-T claims. The required reporting of revenue code 0891 as of April 1, 2019 and ideally CMS agreeing to require hospitals to report value code 86 in the future should greatly facilitate providers more accurately and completely reporting their cell therapy charges and costs. The ASTCT will continue our education efforts to bolster and keep pace with any guidance released by CMS.

By using the concept of a cell therapy drug off-set, not unlike how CMS uses a device off-set today, CMS will be able to avoid creating a separate MS-DRG for T-cell immunotherapy cases

with no product cost, avoid keeping these cases in MS-DRG 016 as we do not believe this is the most appropriate way to pay for these cases, and avoid systematic overpayment in the future for these T-cell immunotherapy cases reported with only a token charge in revenue code 0891. In summary, we are asking CMS to utilize its existing mechanism of applying an “off-set” to avoid overpayments while also creating a only one new MS-DRG for T-cell immunotherapy which is consistent with CMS’ general authority under sections 1886(d)(4)(B) and (C) of the Social Security Act given how vastly different this therapy is both clinically and in its use of resources compared to any other MS-DRG.

The Societies look forward to continuing to work closely with the Agency to find the most equitable and sustainable solutions and discussing our ideas for the immediate future with the agency in the coming weeks. We will also share some of our longer-term ideas of how the agency may need to begin modifying the MS-DRG payment system to accommodate the pipeline of cell and gene therapy products. For any questions please contact ASTCT’s Director of Government Relations, Alycia Maloney, at amaloney@astct.org or ASH’s Chief Policy Officer, Suzanne Leous, at sleous@hematology.org.

Sincerely,



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