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Administrator Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

September 24, 2018

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule (CMS-1695-P)

SUBMITTED ELECTRONICALLY VIA

<http://www.regulations.gov>

Administrator Verma –

The American Society for Blood and Marrow Transplantation (ASBMT) is a professional membership association of more than 2,000 physicians, scientists and other healthcare professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication and clinical standards. The ASBMT is dedicated to improving the application and success of hematopoietic cell transplants (HCT) and other cellular therapies, such as Chimeric Antigen Receptor T-cell therapy (CAR-T).

In this document, the ASBMT provides commentary on the following issues:

- Status Indicator Assignment for CAR-T CPT Codes
- HCPCS Codes for CAR-T Products
- Calculation Methodology for Allogeneic HCT C-APC
- C-APC Request for Autologous HCT
- Cost Center 77 Reporting Instructions Request
- Prior Authorization
- Payment for Pathogen Reduced Platelets
- Competitive Acquisition Program Innovation Center Model

I. Technical Requests for HCT and CAR-T Payment

a. Status Indicator Assignment for CAR-T CPT Codes

In Addendum B, CMS assigned status indicator “B” to the new Current Procedure Technology (CPT) codes created for CAR-T at the American Medical Association’s May 2018 meeting. The CPT panel unanimously supported these codes and acknowledged there are no other codes that describe the clinical services associated with CAR-T. The codes were assigned to Category III due to the limited number of providers currently providing the service and the lack of volume data currently available. The approved codes were released in July and will be effective January 1, 2019¹.

We note that all hospitals and payers must comply with HIPAA Administrative Simplification laws which name the AMA CPT Editorial Panel as the standards setting organization for CPT codes. Furthermore, CPT directs suppliers and providers to “*not select a CPT code that merely approximates the service provided. If no such specific code exists, then report the service using the appropriate unlisted procedure or service code.*” Given this, we believe that from the date of the first CAR-T product’s FDA approval date until January 1, 2019, the most appropriate CPT code for providers to use to report each service associated with CAR-T therapy has been the unlisted CPT code 38999. Beginning January 1, 2019, this will change as it will be appropriate for providers to begin reporting the four new more specific Category III CPT codes that the AMA just approved.

The ASBMT presented this issue to the Advisory Panel on Hospital Outpatient Payment and the HOP Panel recommended that CMS reassign the status indicators (SIs) for the following CPT codes from B to S:

- CPT code 05X1T, *Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day*
- CPT code 05X2T, *Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived lymphocytes for transportation (eg, cryopreservation, storage)*
- CPT code 05X3T, *Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration*
- CPT code 05X4T, *Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*

¹ AMA Documentation: <https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-category3-codes-long-descriptors.pdf>

The Panel further recommended that CMS assign CPT code 05X1T and CPT code 05X4T to APC 5242, *Level 2 Blood Product Exchange and Related Services*, and CPT code 05X2T and CPT code 05X3T to APC 5241, *Level 1 Blood Product Exchange and Related Services*.²

For reference, the payment crosswalk provided for the HOP Panel review, and the APC assignments referenced in their final recommendation is provided below.

CY 2019 OPPTS Proposed Rule Status Indicator and APC Assignment					Recommended Status Indicators and APC Assignments and Payments Based on Using the Transplant Codes as a Cross-Walk				
HCPCS Code	Short Descriptor	CI	SI	APC	HCPCS Code	Short Descriptor	SI	APC	APC Payment
05X1T	Bld drv t lymphcyt car-t cll	NP	B		38206	Harvest auto stem cells	S	5242	\$1,222.97
05X2T	Bld drv t lymphcyt prep trns	NP	B		38207	Cryopreserve stem cells	S	5241	\$383.39
05X3T	Receipt&prep car-t cll admn	NP	B		38208	Thaw preserved stem cells	S	5241	\$383.39
05X4T	Car-t cll admn autologous	NP	B		38241	Transplt autol hct/donor	S	5242	\$1,222.97

The ASBMT wishes to note that while CAR-T is fundamentally different than HCT, the transplant codes provide useful benchmarks of resource utilization, particularly as both sets of clinical services are handled by the same set of physicians. Utilization of these codes as a payment crosswalk reference aligns with CMS’ assignment of CAR-T to MS-DRG 016, Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy

We ask that CMS follow the recommendations provided by the HOP Panel and modify the proposed status indicators for the CAR-T CPT codes. Despite coding suggestions from some manufacturers, ASBMT member clinicians strongly disagree with coding CAR-T services using chemotherapy or transplantation codes since CAR-T is clinically neither and per CPT instruction as stated above, it would be inappropriate to report an approximate code when a more specific code is available. ASBMT member clinicians are also aware of CMS’s current bundling of some of the clinical services associated with CAR-T (“leukapheresis and other dose preparation procedures”) within the drug codes, Q2040 and Q2041. As ASBMT has stated previously, and will detail in the following section, our members remain in strong disagreement with CMS’s bundling of these clinical services into a drug code. Despite the bundling of certain services into the drug Q codes, the actual infusion of the CAR-T drug is not included, making it imperative that CMS assign status indicator “S” to the newly created CPT infusion code 05X4T and cross-walk it to APC 5242 as shown in the table above.

Without being afforded use of new Category III codes, providers will have no other appropriate option other than to submit CPT code 38999, *Unlisted procedure, hemic or lymphatic system* for each of these services. When providers use CPT code 38999, multiple manual processes need to occur on both the side of the provider and the Medicare Administrative Contractor (MAC), including the submission of patient-level clinical documentation, coding reference crosswalks

² CMS.gov Advisory Panel on Hospital Outpatient Payment “August 20, 2018 Agenda, Recommendations, Presentations”: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>

and physician-specific requests for reimbursement. Additionally, neither CMS nor the AMA will receive the charge and volume data it needs to monitor utilization. Additionally, without the use of specific codes, there will be no way to distinguish these services from others also reported with CPT code 38999. At the outset of this entirely new clinical service, CMS has the opportunity to gather clear and specific data on the use and cost of CAR-T; we ask that the Agency follow the recommendations of the HOP Panel and make the aforementioned status indicator modifications in the Final Rule.

b. HCPCS Codes for CAR-T Products

The ASBMT has submitted multiple requests³ to CMS requesting removal of the patient care services (“leukapheresis and other dose preparation procedures”) from the definition of the CAR-T product HCPCS Q-codes for both FDA-approved CAR-T products (Q2040 – Kymriah and Q2041 - Yescarta). Additionally, the ASBMT joined the American Society of Hematology, both CAR-T product manufacturers and multiple providers in protesting the current coding structure at the May 2018 HCPCS Public Meeting. The feedback to CMS at the HCPCS meeting was uniform; there was not a single attendee that spoke in favor of keeping the current coding structure. Despite the common concerns from the provider community and manufacturers, CMS did not modify the codes as requested and continues to use a coding structure that creates a de facto bundled payment, without providing any specific rationale that providers could review and provide comment on. The ASBMT understands that the newness of CAR-T and the manufacturing process may have given CMS initial cause to create the Q code as currently structured for the initial implementation period. However, we ask CMS to revise its position given the more mature understanding of how the provider community utilizes these products and the issues with the current coding structure.

The release of the new CPT codes for CAR-T furthers the case for CMS to create a coding and payment policy separation for the clinical services being provided to the patient and the drug product itself. By making this modification, CMS will reduce unnecessary provider burden associated with the current unusual Q code structure; reporting will be far simpler and in line with all standard claims preparation and cost reporting practices, and will enable the provider who renders the service to report it at the time it was provided.

Reporting Implications of Current Q Code Structure: Our members note that long-standing cost reporting instructions interact with the current CAR-T HCPCS codes and cause significant confusion and questions. For example, an underlying requirement in the Provider Reimbursement Manual Part 1 Section 2202.4 is that hospital charges are “[required to] be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.” Therefore, when hospitals establish their charge for a CAR-T product in their chargemasters, it must be the same dollar amount for both inpatient and outpatient encounters. As CMS has included clinical services in the drug code, including services that may occur in different hospital departments (in some cases at different hospitals altogether), at different times, and during different patient encounters, it is extremely difficult – if not impossible - for hospitals to meet the intent of the HCPCS Q-code and also comply with CMS’

³ ASBMT letters to CMS regarding HCPCS Q codes for CAR-T Products: <http://asbmt.org/practice-resources/coding-and-reimbursement/car-t-therapy>

existing requirements of hospital cost reporting and appropriate charging. We provide some additional detail about the various patient clinical services and the issues providers are facing below.

The leukapheresis procedure to collect the T-cells from the patient typically occurs in a hospital outpatient setting several weeks prior to the CAR-T infusion, which may be provided in either the inpatient or outpatient setting. Following hospital charge and cost reporting requirements, hospitals would typically bill the cell collection service on an outpatient hospital 013x claim for the encounter during which the patient is examined and has their cells collected. The cell processing laboratory of the hospital is then involved in T-cell processing and preparation services prior to the cells being sent to the product manufacturer for genetic engineering. All of the charges for these services would be listed under the appropriate revenue code and would be reported on the hospital's 013x claim with the date of service of the outpatient encounter.

In the case of CAR-T cell therapy, hospitals do not know how to meet the definition of charges quoted above when certain clinical services occur weeks prior to the infusion and when the infusion may occur in the inpatient or outpatient care setting. CMS has not instructed hospitals to hold their patient's cell collection outpatient claims and not bill as they would usually, nor has CMS explained how hospitals should address issues such as cell collection having occurred but the infusion not proceeding either because the patient died or because the cells could not be manufactured, or for other reasons. Under the current coding structure, the hospital is left facing the cell collection cost without any way to recoup payment, as it would not be appropriate to report the Q-code, even with a modifier -52.

Furthermore, it is possible for one hospital to perform cell collection while another provides the administration of the final product. With this situation, hospitals are unclear on who should report the Q-code and how since it is inclusive of the cell collection and cell processing service provided by one hospital and the other cell processing and CAR-T product/drug that would need to be reported by the other hospital. Each hospital must be able to report the individual patient care services it provided to CMS per claims and cost reporting guidelines. Additionally, electronic medical records set up templates for clinical documentation and billing so that a charge is initiated in real-time when a service is provided, and any disruption to this flow of providing services, reporting charges and then billing the appropriate claim represents significant risk and burden to hospitals and could result in erroneous reporting to CMS.

The following are just a few examples of the types of technical questions the ASBMT has received:

- Should the hospital report charges, but no HCPCS code for these services on their outpatient claim billed on the date the service is performed?
- Should the hospital hold the charges from the outpatient encounter that exceed 3 days before the inpatient stay and include them on their inpatient claim? (i.e., Hold the Q-code that begins with an outpatient service and report all charges only on the inpatient claims?)
- Should the hospital report token charges on the outpatient claim and then real charges on the inpatient claim?
- How are hospitals to report cell collection when the cells are not infused?

None of these options would meet current transaction set requirements for reporting patient clinical services on claims and therefore hospitals have raised concerns about how they are to be in compliance with HIPAA transaction code set and claims preparation rules.

Therefore, ASBMT asks that CMS either make the HCPCS code description change requested above, specifically to remove patient care services (“leukapheresis and other dose preparation procedures”) from the definition of the CAR-T product HCPCS Q-codes for Q2040 and or address the issues raised so providers have clear guidance on how to report CAR-T services to CMS in a complete and compliant manner.

Creation of New Cost Center to Align with NUBC Changes: The National Uniform Billing Committee (NUBC) recently assessed the need for changes to provider claims to accommodate new cell and gene therapies. The NUBC is in the process of issuing new revenue codes and other billing changes that will support the use of clear and consistent reporting of the patient care services associated with providing CAR-T as well as the actual drug products administered. In light of these changes, which we anticipate becoming final in first or second quarter 2019, CMS should create a new cost center for providers to use in conjunction with the NUBC changes and release detailed cost reporting instructions. If CMS decides to continue with including clinical services in the CAR-T product Q-codes, clear cost reporting instructions will be critical given the exceptional financial processes required. The ASBMT asks that CMS release all relevant and applicable guidance in a separate transmittal dedicated to CAR-T issues, similar to what the agency previously released for drug administration services.

Q Code Adjustment for Pediatric and Adult Cell Volumes and Indication-Based Pricing:

Additional questions have been raised as to how providers are to properly report the HCPCS Q code for Kymriah when used to treat a Medicare patient for relapsed/refractory Diffuse Large B-cell Lymphoma (DLBCL). At the May HCPCS meeting, Novartis presented a request to CMS for a new or modified code that would reflect the difference between the cell volumes utilized in the Pediatric Acute Lymphoblastic Leukemia (B-ALL) indication and the DLBCL indication. The current long descriptor of HCPCS Q2040 is “*Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion*” and Novartis requested a modification of language to “*Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion*” to be inclusive of the T-cell count typically given to adult patients.

In order to allow accurate billing practices for the indication-based pricing and cell volume differences, CMS must either update the description as requested, or – preferable - release a separate Q-code reflective of the appropriate cell dose for the DLBCL and pricing. This creation of separate codes would truly enable CMS to provide indications-based payments reflective of the two separate NDCs for each indication of Kymriah. Commercial payers are engaging in indications-based payment as they use the reported NDC on the claim to differentiate when they should pay a higher amount to cover the provider’s acquisition cost for the pediatric indication vs. the lower cost for the adult indication. If CMS does not do this, then we urge the agency to provide detailed guidance to the provider community on what it expects with respect to HCPCS reporting when Kymriah is given to the adult population, particularly if infused in the outpatient setting since the Q-codes and reported units of service impact payment.

Specifically, our members are questioning the appropriateness of this HCPCS code for adults with r/r DLBCL where dosage amounts extend to the upper range of 600 million T cells given their literal read of CMS' current instructions concerning proper reporting of drug units found in Section 10.40 of Chapter 17 of the Medicare Claims Processing Manual which states,

“If the provider furnishes a dose of a drug that does not equal a multiple of the units specified in the HCPCS code for the drug, the provider should round to the next highest unit when reporting the drug.”

Because of this instruction and the current description of Q2040, hospitals are justifiably asking how they are to report units of service appropriately when they furnish a 600 million T-cell dose of Kymriah to treat a Medicare DLBCL patient. Specifically, they are asking if they should bill CMS three units of Q2040 to be compliant with CMS' requirements stated above. If they were to do this, it could result in a Medicare allowable of the current APC payment rate of \$500,838 times three resulting in a total payment of \$1,502,516. The ASBMT does not believe this is appropriate nor do we believe this is CMS' intent, particularly given the existence of a known system edit limiting payment to one product unit per date of service, but we consider this is a fair question that should be addressed by CMS.

An alternative process would be that hospitals bill HCPCS C9399 and the unique NDC for the Kymriah adult lymphoma indication, which would then result in providers being paid 95% of AWP rather than the ASP+6% associated with Q2040 (Addendum B; \$500,838). This seems more logical and far more appropriate from a Medicare perspective as the product price for the adult indication is \$373,000 and the Addendum B published amount for Q2040 is based on the ASP information that to date has only been available for the pediatric product. However, the Q code for the CAR-T product would not come through on the treatment claim making it more difficult for CMS to track the data and monitor utilization.

It may be that CMS simply expects providers to report Q2040 as it is and considers the \$500,833 payment amount appropriate despite it being far in excess of the \$373,000 cost that hospitals bear. This also seems unlikely given CMS' concerns about drug pricing and payment issues and its desire to be a prudent purchaser of healthcare services, but it furthers the case for CMS to clarify the issue and release specific guidance as it is inappropriate to leave hospitals to determine which rules/regulations take precedence over others and navigate the billing of outpatient CAR-T using one of the following options:

- (a) Report 3 units of Q2040 and get significantly over-paid but remain compliant with guidance in Section 10.40 of Chapter 17 of the Medicare Claims Processing Manual.
- (b) Report 1 unit of Q2040 in recognition that this is the best code available at present
- (c) Report 1 unit of C9399 and the NDC and get paid 95% of the AWP

It is important that CMS understand the lengths hospitals, and particularly our members, go to in ensuring they accurately and compliantly report codes and claims to CMS. Further, the compliance-oriented set of best practices is under extreme scrutiny due to the high cost of the products that need to be appropriately reported. By outlining this issue in detail above we hope

CMS understands the complexities that have been introduced by the current set of Q codes and the ASBMT's role in attempting to help member providers sort through them. However, in the absence of clear information from CMS, the ASBMT is unable to provide any definitive resource to providers.

To assist providers with accurately and appropriately billing for CAR-T products, we request CMS create a second code for Kymriah by working with Novartis to appropriately and fully describe the cell dose for DLBCL and that this new code only reflect the drug, for previously stated reasons. This will be the simplest, easiest, and most transparent way for providers to report Kymriah for DLBCL and for Medicare to provide appropriate payment. Finally, as more cell and gene therapies are expected to utilize indication-specific pricing, CMS would be proactively setting up a coding precedent that could be mirrored with additional products and indications.

c. Calculation Methodology for Allogeneic HCT C-APC

In an analysis conducted by our colleagues at the National Marrow Donor Program, an unintentional error in the rate-setting process for the existing allogeneic transplant C-APC (C-APC 5244) was discovered. CMS' stated intention with the creation of the C-APC for Allogeneic HCT was to include all costs of care associated with outpatient provision of stem cell transplantation. These costs include all charges associated with the identification, collection and transport of the donor cells used in HCT. In CY 2017, CMS assigned a new revenue code (0815) for the reporting of donor search and cell acquisition costs associated with allogeneic transplant. Revenue code 0815 is not typically associated with a HCPCS code and as a result should have been added to CMS' packaged revenue code list but it appears it inadvertently was not.

As a result, our understanding from the NMDP's analysis is that only 19 claims from CY 2017 were utilized for CY 2019 rate-setting despite there being 36 single procedure claims available in the data set that followed CMS' reporting instructions for C-APC 5244; specifically that the claim must contain the presence of revenue code 0815 and CPT code 38240 but with no specific requirement that revenue code 0815 must have a HCPCS code billed with it. As a result, we ask CMS to make a technical rate-setting correction and add revenue code 0815 to its packaged revenue code list and recompute the payment rate for C-APC for CY 2019.

If CMS wants hospitals to definitively report a HCPCS code with revenue code 0815, we ask CMS release detailed instructions to transplant centers and establish a claim coding edit going forward. If CMS proceeds in this manner, we recommend the agency indicate that HCPCS code 38204 be the appropriate code to report in this case. We note that this code has a status indicator "N" and is considered packaged; code 38204, *management of recipient hematopoietic progenitor cell donor search and cell acquisition*, and would be the most accurate code to describe the services that make up the charges reported within revenue code 0815.

d. C-APC Request for Autologous HCT

In alignment with CMS' creation of the C-APC code 5244 for outpatient allogeneic HCT, CMS should create a new comprehensive APC (C-APC) for autologous stem cell transplantation

(AutoHCT). AutoHCT meets the general guidelines that CMS has set forth for C-APCs, including that it involves a relatively standard set of clinical services that occur on the same date of service as the transplant, including labs, cell processing, drug administration services, and others. The creation of a new C-APC for AutoHCT would support CMS' stated goal to create larger service bundles and to use accurate, comprehensive data in the rate-setting process.

The National Marrow Donor Program raised this issue at the HOP Panel in August 2018, after identifying that only 14 single procedure claims out of 379 total claims were used to set the CY 2019 AutoHCT APC payment (APC 5241, associated with CPT code 38241). The recommendation from the HOP Panel was as follows:

*The Panel recommends that CMS study the appropriateness of creating a comprehensive APC for autologous hematopoietic stem cell transplantation.*⁴

While CMS could study the issue in the upcoming year, providers would welcome any initiative CMS would take in the creation of a new C-APC in the CY 2019 Final Rule.

e. Cost Center 77 Reporting Instructions Request

CMS issued a new reference document (Transmittal 12, November 17, 2017, Part 2 Provider Cost Reporting Forms and Instructions) to support the creation of dedicated cost center 77, effective as of January 1, 2017. We ask that CMS provide further manual instruction to hospitals on how to correctly aggregate donor search and cell acquisition costs to this cost center. Identifying donor expense is straightforward for unrelated donor cells, because it is a purchased service from the NMDP and individual invoices for these services are sent to the hospital. In contrast, when providers work up related donors (such as siblings or other family members) in house, they have no guidance on how costs should be reclassified from individual departments that treated related donors (such as lab, clinics, etc.) and then aggregated in the new cost center.

In conjunction with this set of instructions, we ask CMS to address Section 231.11.1 of Chapter 4 of the *Medicare Claims Processing Manual*. The text lists “Physician pre-procedure donor evaluation services” as an example of acquisition costs for allogeneic HCT. We do not believe that these costs should be reported as facility costs in the new cost center 77. Transmittal 1805—which CMS has republished on its webpage as recently as March 22, 2018—discusses billing for allogeneic HCT and 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. The ASBMT agrees with this classification of physician pre-procedure donor evaluation services as Part B professional services. If pre-procedure donor evaluation services by physicians are Part B professional services, as stated in Transmittal 1805, then the costs associated with these services should be billed in real-time rather than being held until the transplant recipient’s claim. In summary, these costs should not be reported as a hospital “cost” on the hospital claim or in the hospital’s cost report in cost center 77 and CMS should

⁴ CMS.gov Advisory Panel on Hospital Outpatient Payment “August 20, 2018 Agenda, Recommendations, Presentations”: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>

make this clear by removing this service from Section 231.11.1 of Chapter 4 of the *Medicare Claims Processing Manual*.

f. Prior Authorization

In its discussion of an increase in outpatient services, CMS states (p. 37143): “*Prior authorization is a requirement that a health care provider obtain approval from the insurer prior to providing a given service in order for the insurer to cover the service. Private health insurance plans often require prior authorization for certain services. Should prior authorization be considered as a method for controlling overutilization of services?*”

While there may be merit in considering the implementation process of a binding prior authorization process for transplant indications not currently addressed in the National Coverage Determination, prior authorization processes are a frequent source of frustration for providers and most often result in burdensome paperwork, delays in beneficiary access to care and additional cost with interim treatments associated with delayed decision-making. Instead of prior authorization processes, we ask that CMS solicit feedback from providers on the noted changes in their practice patterns and use that information to assess potential payment structure changes.

g. Payment for Pathogen Reduced Platelets

The ASBMT supports AABB, America’s Blood Centers and the American Red Cross in their request to correct the erroneous reimbursement rate for pathogen reduced platelets (P9073) by crosswalking P9073 to P9037 (leukoreduced, irradiated apheresis platelets) for 2019 and 2020.

The analysis conducted by the aforementioned organizations has found that incorrect claims data from four high-volume hospitals, which collectively submitted 1,267 of the 2,772 total claims for Medicare outpatient pathogen reduced platelet units in 2017, resulted in CMS establishing an incorrect and artificially low reimbursement rate for pathogen reduced platelets for 2019. CMS should utilize the crosswalk for P9073 in CY 2019 and CY 2020 until further investigation and correction of the claims data issue has been completed.

II. *Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model*

The ASBMT wishes to first acknowledge CMS’ on-going demonstration of a willingness to consider unique solutions and payment methodologies for high cost drugs and biologicals, such as CAR-T. We also note that CMS may consider re-issuing the Request for Information (RFI) separate from a standard payment system rule-making cycle and after incorporating initial feedback from stakeholders. CMS issued over 30 separate questions for stakeholder input, all of which could readily fill months of analysis and discussion; it was not possible to fully vet the ideas and questions presented by CMS in addition to the already complex and wide-ranging nature of the OPPS payment issues discussed in the Proposed Rule.

The ASBMT represents the clinical community that cares for patients receiving CAR-T throughout their episodes of care. As our member providers are the first line purchasers of the CAR-T products and are financially responsible for the product costs, the ASBMT has been closely tracking the coding and reimbursement issues associated with CAR-T to understand the impact of CMS' current reimbursement policies. In our comments to CMS regarding the Fiscal Year 2019 Inpatient Prospective Payment System Proposed Rule, we supported a methodology that included payment for the episode of care, including the usual outlier calculations, and separate invoice- or ASP-based payment for the CAR-T product. The rationale for this request was that the products are autologous (i.e. beneficiary-specific) and manufactured on-demand, which means that providers are paying full list price, without the ability to stockpile or leverage bulk-buying discounts.

In the FY2019 IPPS Final Rule, CMS stated

Building on President Trump's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, the CMS Center for Medicare and Medicaid Innovation (Innovation Center) is soliciting public comment in the CY 2019 OPSS/ASC proposed rule on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out of pocket spending. CMS sought similar feedback in a previous solicitation of comments, and, most recently, in the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Given the relative newness of CAR T cell therapy, the potential model, including the reasons underlying our consideration of a potential model described in greater detail in the CY 2019 OPSS/ASC proposed rule, and our request for feedback on this model approach, we believe it would be premature to adopt changes to our existing payment mechanisms, either under the IPPS or for IPPS-excluded cancer hospitals, specifically for CAR T cell therapy.

Per CMS' request, the ASBMT reviewed the relevant section of CMS-1695-P (Proposed Rule) and wishes to offer the following commentary on *Section C. Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model.*

General Comments

We understand and support CMS' desire to influence the extraordinary costs associated with the current CAR-T products, particularly in the context of the outpatient setting and its associated ASP +6% framework. However, the ASBMT has several general concerns with the CAP and CAP-like Drug Value Program (DVP), *as described in this RFI language*, for the purposes of mediating the costs of CAR-T. We remain committed to engaging with CMS in discussions of joint agency-provider proposals and models to reduce the potentially negative impact to the solvency of the Medicare program that is currently associated with high-cost innovative therapies.

The vast majority of CAR-T patients currently receive their therapy in the inpatient setting and will continue to do so for the next several years. Even if these individuals received their infusion in the outpatient setting, the vast majority are expected to be admitted to the inpatient setting

within 24-72 hours based on provider experience to date, resulting in the outpatient administration claim charges being added to the inpatient claim and claims processing and payment occurring under the MS-DRG payment system. If CMS continues to assess how it may use the authority associated with the CAP program to explore DVP-like models, it will need to clarify how CMS' envisions utilizing these programs *across sites of care* to address the most significant points of financial distress that providers are facing by treating patients in the inpatient setting. ***As previously stated in our comment letters and conversations with CMS/CMMI staff and leadership, the ASBMT would welcome the opportunity to work with CMS and CMMI on a demonstration project that can utilize aspects of the DVP, such as outcomes- or reporting-based payment, shared savings, and burden reduction in a site-neutral manner that facilitates a provider-driven election of the product and the site of care most appropriate for the illness and condition of the beneficiary.***

We acknowledge that the percentage of CAR-T therapy administered in the outpatient setting will grow over the next several years, as toxicity prevention, management and product safety profiles improve. This may be precisely why CMS may be interested in implementing a CAP-like program to address the concerns of high-cost products like CAR-T. We are concerned about the financial incentivization to shift CAR-T patients to the outpatient setting that has been created by the current inpatient payment structure; the anticipated shift in care settings should be allowed to happen organically, as provider expertise with the therapeutic process matures and only when appropriate for the individual patient being treated. Financial incentivization to a specific care setting for a new technology could result in hasty site of care transitions that may not be in the best clinical interests of the beneficiaries needing treatment or the financial well-being of the Medicare program. Some providers may respond to the financial pressures of the deficient inpatient payments by electing to use the CAR-T product with a longest average time to toxicity onset, which may allow them to receive full outpatient payment for the drug product (at the ASP+6% level), mitigate early toxicities through outpatient care and receive separate payment for any inpatient stays necessitated by the appearance of more severe toxicities that appear after the 24 hour (Exempt hospitals) or 72 hour (PPS hospitals) mark post-infusion. Product selection would ideally be driven by long-term clinical data on efficacy, not by deficient reimbursement mechanisms.

We are concerned that this particular vein of innovation projects will result in the same results as experienced previously – namely a lack of overall savings demonstrated by the project. There are currently only two approved products, each of which has the same list price and approved indications, and no generic or allogeneic universal products; the opportunity for price competition in this space is likely restricted, particularly with limited data on long-term clinical outcome differences between the two. If CMS is successful in encouraging manufacturers and the majority of providers to participate in the project, the ASBMT fears the market will adjust pricing based on the anticipated discounting that will be applied through the vendor relationship in the same way that 340B program discounts are accounted for in list pricing decisions today.

Applicability of CAP/DVP to Certain Classes of Therapeutics: While we appreciate CMS recognizes the limitations of the original CAP program and acknowledges that a new model, such as the DVP or some new hybrid model will likely be necessary, the ASBMT does not feel that CAR-T is an appropriate candidate to be included in the classes of drugs being considered

for a CAP/DVP like program primarily due to the many unknowns that exist with this new and emerging therapy. At a very basic level, it is difficult to see how a CAP/DVP like program would work for individualized autologous products where patient's own T-cells are collected and genetically engineered to target a specific tumor-associated antigen. Cells are collected from patients via leukapheresis and then delivered to the manufacturer where the molecularly engineered receptors are inserted into the cells and then reproduced, a process that takes weeks. The new CAR T-cells are then returned to the hospital where they are infused into the patient. This on-demand creation of a patient-specific product, one that cannot be used for other individuals or stockpiled, is high-risk for the manufacturer, the patient and the provider. Health systems have been unable to leverage their usual purchasing power and discount negotiations for this class of therapeutics and we believe vendors would face the same issue with the current limited range of products and volumes across which to find the anticipated cost savings.

Vendor Title Ownership and Direct Manufacturer-Provider Transfer: The CAR-T product procurement process is already very complex, requires special adherence to an FDA-approved chain of custody process and is billed through legal contracts between the manufacturer, treatment center and specialty pharmaceutical company. Introduction of an external vendor with additional legal conditions and procedures associated with holding the title of the drug will almost assuredly create systemic delays and complications that increase the risk of delayed or incorrect shipments, manufacturing, receipt and/or administration, none of which are in the best interest of the beneficiary awaiting treatment. We appreciate CMS' intent to remove the financial responsibility of the product cost from the provider, but strongly believe the regulatory procedures associated with CAR-T and the current time sensitive nature of the product manufacture and handling will not likely make for a good fit for an additional vendor model. With additional time and discussion, our members may be able to suggest ways in which the current system could flex to meet the design framework of CAP/DVP, particularly if the model were introduced in a site-neutral way. The complexity in processes and urgency associated with these products already requires disproportionate administrative and clinical resources within the current treatment communities – introducing another level of complexity specific to only one site of care would be a non-starter for the majority of providers.

Beneficiary Cost-Sharing: The pricing of CAR-T means that beneficiaries will pay the maximum inpatient deductible equivalent. Even with substantial discounts off of list price, the price will remain at a point where patients are responsible for the full inpatient equivalent. Thus, the use of CAP or DVP model in the way currently proposed will not facilitate beneficiary cost-sharing savings.

Product Coding Structures to Support CAP: While it was not a specific question posed by CMS, the ASBMT feels compelled to note that the current coding framework that CMS has developed for CAR-T will not align with its stated interests in the utilization of a CAP/DVP type program or for future outcomes-based payment models. The CAR-T product code, currently a Q-code, would need to be revised to exclude clinical services (“leukapheresis and other dose preparation procedures”) in order to be effectively utilized in any specialized program focusing on drug payment as described in detail above. The legislative authority CMS refers to specifically references drugs, whereas current CAR-T product codes couple the drug/product and several clinical services. Additionally, the reconciliation process outlined by CMS in the discussion of



CAP-like models is driven by the billing of the administration code by the provider on behalf of the beneficiary. As noted previously in this letter, CMS is not currently planning to recognize four Category III CPT codes released for January 1, 2019 implementation for the provision of various CAR-T services, including the administration of CAR-T represented by placeholder CPT code 05X4T. Regardless of which innovation project CMS chooses to pursue, it should support the utilization of specific and separate coding structures to allow for detailed reporting, data analysis and cost transparency for the drug products separate from the clinical services rendered to patients. In other words, CMMI will not be able to design a successful program without coding and payment system alignment.

Conclusion

The ASBMT reiterates our previous requests to CMS for a site-neutral reimbursement policy for CAR-T and other autologous, personalized cellular therapies, and our interest to partner with the Agency on payment mechanisms that support our member clinicians in their desire to provide the optimal individualized care plan for each beneficiary in need of CAR-T. Our physician leaders are currently discussing potential alternative payment models that more accurately reflect the opportunities for value and clinical quality differentiation in these episodes of care and anticipate submitting those proposals to CMMI for review within the next several months.

As always, ASBMT leadership and members are available as a resource to CMS on any of these issues. Please contact Stephanie Farnia, Director of Health Policy (SFarnia@asbmt.org) with any questions or requests for additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "John DiPersio", is positioned below the word "Sincerely,".

John F. DiPersio, M.D., Ph.D.

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