



American Society for Blood and Marrow Transplantation  
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June 22, 2018

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1694-P  
P.O. Box 8011  
Baltimore, MD 21244-1850

Re: CMS-1694-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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Administrator Verma:

The American Society for Blood and Marrow Transplantation (ASBMT) 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 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).

## **I. Summary of Comments**

The ASBMT sincerely appreciates CMS' detailed discussion in the FY 2019 Inpatient Prospective Payment System (IPPS) Proposed Rule to address the inadequate reimbursement for CAR-T episodes. The current inadequate reimbursement is based, in part, on variable MS-DRG assignment for CAR-T cases, the lack of a New Technology Add-on Payment (NTAP) and - most significantly - charge compression of the product acquisition cost. We recommend that CMS adopt the following changes to pay more appropriately for CAR-T cases in FY19.

1. The ASBMT recommends that CMS use the proposed concept of a CCR of 1.0 to ensure adequate reimbursement is provided to both PPS-hospitals and PPS-Exempt hospitals. For PPS hospitals, CMS can implement a CCR of 1.0 using a separate, add-on payment for CAR-T, based on ASP or actual acquisition cost. For PPS-Exempt hospitals CMS can implement a CCR of 1.0 using specific cost-reporting processes outlined by the

Alliance of Dedicated Cancer (ADCC) in its comment letter. This will ensure that the agency can clearly identify the hospital's cost of acquiring the therapy and reimburse for it accordingly.

2. The ASBMT recommends that CMS finalize its proposal to assign CAR-T cases to MS-DRG 016 for the next two to three years while data are collected and further analyzed before determining how to proceed with future CAR-T specific MS-DRGs.

As we discuss in greater detail later, our recommendations are a logical outgrowth of the issues discussed in the proposed rule, including CMS' interest in considering and receiving comments on alternative approaches to determining payment for CAR-T cases. We believe that CMS can make these changes under the broad authority to make necessary adjustments in IPPS payments provided by Congress in section 1886(d)(5)(I)(i) of the Social Security Act.

In addition to our recommendations regarding payment for CAR-T cases, we also provide recommendations for improved payment of hematopoietic stem cell transplants (HCT). Specifically, we recommend that CMS better align payment for HCT with payment for other types of organ transplantation. We request CMS adopt changes to the way it processes and uses HCT claims to rate-setting purposes to more accurately estimate the cost of HCT cases.

Finally, based on our considerable experience advising patients about financial costs of care for stem cell transplants and other cellular therapies, we recommend that CMS not put additional requirements on providers to publish charges. In the absence of appropriate counseling, we do not believe that patients will have an appropriate understanding of the charge information or of how charges relate to cost and patient cost-sharing. Posting of charge information without context and counseling could lead patients to avoid receiving care because of a misunderstanding of the financial cost.

## **II. CAR-T Proposals**

### **a. Transformation in Clinical Care**

In late 2017, the FDA approved the first two CAR-T products for use in the treatment of specific blood cancers. While much of the focus since that time has been on reimbursement issues associated with the therapies, we wish to acknowledge the truly transformative effect of CAR-T on the clinical options for patients with certain types of lymphoma. Historically, rates of complete remission in highly refractory Non-Hodgkin lymphoma (NHL) patients are less than 10%; the data associated with the approval of the current products indicated complete remission rates near 50%.

The FDA noted the uniqueness of CAR-T when it approved tiasgenlecleucel (KYMRIA®<sup>®</sup>, Novartis) in August 2017:

The U.S. Food and Drug Administration issued a historic action today making the first gene therapy available in the United States, ushering in a new approach to the treatment of cancer and other serious and life-threatening diseases. "We're entering a new frontier

in medical innovation with the ability to reprogram a patient’s own cells to attack a deadly cancer,” said FDA Commissioner Scott Gottlieb, M.D.”

Upon the approval of axicabtagene ciloleucel (YESCARTA™, Gilead) in October 2017, the FDA made this additional statement:

The approval of Yescarta brings this innovative class of CAR-T cell therapies to an additional group of cancer patients with few other options – those adults with certain types of lymphoma that have not responded to previous treatments,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research (CBER).”

#### **b. Summary of CAR-T Medicare Reimbursement Issues**

Provision of the first approved CAR-T products to Medicare beneficiaries sits at the convergence of a set of uniquely difficult reimbursement system conditions that require innovative approaches to address. 1) Based on the approved indications, Medicare beneficiaries will likely make up a significant portion of the CAR-T population. The median age of diagnosis for the approved indication of relapsed/refractory Diffuse Large B-cell Lymphoma (DLBCL) is 70 years of age. Even if a significant proportion of those over age 70 are ineligible for CAR-T due to comorbidities or poor health status, general expectations are that at least 50% of CAR-T recipients will be Medicare beneficiaries. 2) The vast majority of providers have determined that CAR-T currently needs to be furnished in the inpatient setting due to monitoring and treatment of therapy-associated toxicities. 3) These inpatient administrations of CAR-T are happening only at a select subset of hospitals around the country, concentrating the individuals seeking CAR-T within a region at one or two facilities. CAR-T administration is most often housed within a certified facility’s cellular therapy or HCT program, compounding the financial losses those programs already face from the provision of autologous or allogeneic HCT to a growing number of Medicare beneficiaries. 4) The cost associated with acquiring the CAR-T product is beyond the provider community’s usual potential ability to leverage discounts since they cannot buy in bulk, sole source, or otherwise seek reduced pricing for these personalized, autologous and gene modified cell-based drugs.

The current inpatient reimbursement for CAR-T has created a situation in which hospitals providing CAR-T to beneficiaries face unsustainable losses (\$100,000-\$300,000+) *on each and every case*. The cost of the CAR T cells, which constitute the largest portion of the cost of these cases is beyond the control of providers and cannot be made up by efficiencies in the cost of post administration care. As a result, *all* hospitals providing CAR-T— both PPS-hospitals and PPS-Exempt hospitals— are suffering and require a reimbursement solution for FY 2019. We recognize the solution will need to be implemented differently for PPS-hospitals and PPS-Exempt hospitals due to their respective reimbursement structures and we encourage the Agency to implement a payment solution that mitigates the current financial losses for *all* providers.

CMS’ thoughtful discussion in the IPPS Proposed Rule clearly indicates that the Agency recognizes the severity of the current situation and has heard providers’ concerns about this situation. We were especially pleased that CMS described several options to improve

reimbursement in FY 2019, which allowed stakeholders the opportunity to analyze these various alternatives for their real-world impact. We also appreciate the agency being willing to consider “*alternative approaches and authorities to encourage value-based care and lower drug prices.*”<sup>1</sup>

CAR-T products represent a new class of therapies that will evolve over time. Several new products are expected to receive FDA approval in the next two years and we will likely see competition between products, along with increased provision of CAR-T in the outpatient setting. Right now, however, the current approach to caring for CAR-T patients requires exceptional payment policy solutions to ensure access to this life-saving anti-cancer therapy. To resolve this situation, the ASBMT believes that CMS *must* act immediately to change how reimbursement for CAR-T occurs. Several of the options that CMS is considering will require the agency to make adjustments under Section 1886(d)(5)(I) of the Social Security Act (discussed further below), and we strongly recommend that the agency do so. Taking such steps now, when this new class of therapies has first been introduced, will ensure the IPPS structure appropriately evolves to address reimbursement, data tracking, analysis and rate-setting for these innovative therapies.

### **c. Current State of CAR-T Reimbursement**

Providers are in the position of being first-line payers for the CAR-T products and then seeking reimbursement after the completion of the episode of care. Given that both FDA-approved CAR-T products indicated for DLBCL have a published price of \$373,000, providers treating Medicare beneficiaries face excessive losses even after outlier payments and standard adjustments.

The clinical safety profile associated with CAR-T means that it is currently being provided primarily in the inpatient setting so providers can monitor and quickly initiate treatment for Cytokine Release Syndrome (CRS) and neurotoxicity. A minimum inpatient stay for these patients will typically be of 5-7 days, as this is the average time during which CRS and neurotoxicity appear. Inpatient stays may be 2-3 times that long depending on the need for treatment of apparent toxicities. The infusion itself can sometimes be safely administered in the outpatient setting, but as the majority of patients treated experience some degree of CRS or neurotoxicity, admission as an inpatient within the 3-day (PPS) or 1-day (Exempt) window would result in inpatient reimbursement systems being triggered regardless. As a result, the outpatient services will be included on the inpatient claim. Providers cannot yet reliably predict which patients will exhibit CRS or neurotoxicity, so this cost driver is beyond their control.

The drug costs and the tremendous financial uncertainty associated with the provision of CAR-T to Medicare beneficiaries have caused providers to consider and/or employ a variety of potential strategies in an attempt to necessarily insulate their cell therapy program and hospital from financial hardship. We commend those providers which have chosen to treat all clinically eligible patients the same regardless of payer type, pending anticipated reimbursement changes starting in FY 2019. However, we note that other responses have been deemed understandably

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<sup>1</sup>\* CMS FY2019 IPPS Proposed Rule, Federal Register Vol. 83, No. 88, p. 20583

necessary by providers based on the current Medicare situation. Some centers are requesting that Medicare beneficiaries sign Hospital Inpatient Notices of Non-Coverage (HINN) before receipt of CAR-T, others are attempting to understand the ratio of non-Medicare patients (i.e., commercial or private pay international patients) to Medicare patients needed to offset losses and others have decided to provide CAR-T only within the context of clinical trials because the financial losses associated with the approved products is too great. ASBMT's members have reported uniformly close scrutiny by hospital financial leadership of CAR-T, in some cases resulting in the setting of limitations on the number of CAR-T administrations provided until reimbursement has been received and evaluated for sufficiency.

The cumulative result of hospitals' varying responses to the financial uncertainty associated with providing CAR-T to beneficiaries is that individual Medicare patients are facing challenges in locating facilities that are willing to proceed with CAR-T treatment. These patients are very ill, have already failed prior treatments and do not have a line of sight into the financial and administrative variances between facilities; thus, they may face barriers to care at one facility and assume they would face the same delays at all other facilities. With limited time and resources, any barriers that extend the time to treatment are very concerning. *Beneficiaries who need of CAR-T should not have to face these kinds of financial and administrative barriers to care.*

#### **d. CMS Has the Authority to Implement New Solutions to Address this Problem**

Given the inadequacy of existing mechanisms to produce an appropriate payment rate for CAR-T cases, the ASBMT recommends that CMS use the adjustment authority provided by Congress to adjust the IPPS payment for CAR-T cases.

Specifically, under 1886(d)(5)(I)(i), Congress gives the Secretary of the Department of Health and Human Services (HHS) the authority to “provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.” This authority gives the Secretary and CMS considerable flexibility and discretion in determining the need for, and application of, an exception or adjustment. Congress did not place any explicit restrictions on the use of this authority, which CMS acknowledges by regularly describing this authority as “broad.”<sup>2,3,4</sup> CMS has used this statutory authority to make adjustments to address a variety of situations, including to resolve particular geographic reclassification issues;<sup>5,6</sup> to apply documentation and coding adjustments to hospital-specific rates;<sup>7</sup> and to account for shifts in utilization between inpatient and outpatient hospital settings resulting from the two midnight rule.<sup>8</sup> In making these adjustments, CMS acknowledged that its

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<sup>2</sup> 69 Fed. Reg. 49104, August 11, 2004.

<sup>3</sup> 75 Fed. Reg. 50070, August 16, 2010.

<sup>4</sup> 78 Fed. Reg. 50516, August 19, 2013.

<sup>5</sup> 69 Fed. Reg. 49104, August 11, 2004.

<sup>6</sup> 71 Fed. Reg. 48071, August 18, 2006.

<sup>7</sup> 75 Fed. Reg. 50070, August 16, 2010.

<sup>8</sup> 78 Fed. Reg. 50953, August 19, 2013.



“...exceptions and adjustment authority should not be routinely used in the IPPS system”,<sup>9</sup> but determined that the specific circumstances presented were “unique”,<sup>10,11,12,13,14</sup> “extraordinary”,<sup>15</sup> or “systemic”<sup>16</sup>—and therefore justified the adjustments.

CMS clearly has the authority to make needed adjustments under 1886(d)(5)(I) to pay more appropriately for these cases and we strongly recommend that CMS use that authority to make the adjustments described below.

#### **e. Evaluation of Proposed Options**

In the Proposed Rule, CMS outlined several alternatives to address CAR-T reimbursement in FY 2019:

- a) Assignment of an NTAP to CAR-T products;
- b) Assignment of CAR-T claims to MS-DRG 016;
- c) Implementation of a cost-to-charge ratio (CCR) of 1.0 for CAR-T products;
- d) Creation of a new MS-DRG that incorporates a portion of the product cost; and
- e) “Alternative approaches and authorities to encourage value-based care and lower drug prices.”<sup>17</sup>

The ASBMT began our evaluation by first identifying key policy objectives to use when assessing all options. Our overarching objective is to develop a CAR-T reimbursement structure that supports patient access, enables providers to choose the most appropriate combination of product and care settings for specific patients and addresses the challenges created by the current reimbursement policies.

Specifically, the ASBMT determined that any solution for FY 2019 must meet all of the following objectives:

- Create a site-neutral, product-agnostic payment structure that eliminates incentives tied to site of care.
- Maintain appropriate reimbursement for other cellular therapies, including hematopoietic cell transplantation.
- Ensure the system and policies are flexible enough to accommodate future products and scientific advancements within this area.

Next, the ASBMT carefully reviewed the options CMS presented in the Proposed Rule. We modeled the fiscal impact of placing CAR-T cases in MS-DRG 016 in FY 2019 and of granting

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<sup>9</sup> Ibid.

<sup>10</sup> 69 Fed. Reg. 49104, August 11, 2004.

<sup>11</sup> 71 Fed. Reg. 48071, August 18, 2006.

<sup>12</sup> 78 Fed. Reg. 50953, August 19, 2013.

<sup>13</sup> 81 Fed. Reg. 57058, August 22, 2016.

<sup>14</sup> 82 Fed. Reg. 38188, August 14, 2017.

<sup>15</sup> 69 Fed. Reg. 49104, August 11, 2004.

<sup>16</sup> 78 Fed. Reg. 50953, August 19, 2013.

<sup>17</sup> CMS FY2019 IPPS Proposed Rule, Federal Register Vol. 83, No. 88, p. 20583

an NTAP for CAR-T. We were able to examine the impacts of an NTAP per the current formula, outlier payments for simple vs. more complex cases, and providers' low vs. high mark-up practices.

We identified various ways in which CMS could achieve the goal of eliminating or neutralizing charge compression by using a CCR of 1.0, as CMS did not provide a proposed methodology. Additionally, there are no CAR-T cases in the FY 2017 claims data set to either analyze or use as the basis for future rate-setting. We interpreted CMS' statement about using a CCR of 1.0 to mean that the agency understands, and is willing to consider, that the CAR-T product costs used to determine payment to hospitals should represent *actual expense the hospital incurred*. Hence, the ASBMT operated under the assumption that CMS was interested in finding a mechanism to develop a FY2019 payment methodology that would recognize providers' true acquisition cost, rather than a compressed version of that cost.

Of the modeled scenarios, only one option met all of our objectives. Other proposed options resulted in excessive product-based payment variation driven by standard adjustments, failure to meet the ASBMT's objectives of a product-agnostic, site neutral reimbursement structure or continued to produce severely inadequate payment rates.

#### **f. Recommended Path Forward**

The ASBMT recommends that CMS use the proposed concept of a CCR of 1.0 to ensure adequate reimbursement is provided to both PPS-hospitals and PPS-Exempt hospitals. For PPS hospitals, CMS can implement a CCR of 1.0 using a separate, add-on payment for CAR-T, based on ASP or actual acquisition cost. For PPS-Exempt hospitals CMS can implement a CCR of 1.0 using specific cost-reporting processes outlined by the Alliance of Dedicated Cancer (ADCC) in its comment letter. This will ensure that the agency can clearly identify the hospital's cost of acquiring the therapy and reimburse for it accordingly.

The ASBMT also recommends that CMS finalize its proposal to assign CAR-T cases to MS-DRG 016 over the next two to three years, while data are collected and further analyzed, before determining how to proceed with future CAR-T specific MS-DRGs.

We outline our rationale for these recommendations in the following sections.

#### Rationale for Providing Separate Add-On Payment of the Product Cost

As we described previously, the current CAR-T products are autologous, genetically modified cellular biologics that cannot be purchased in bulk to create a discounted acquisition cost or otherwise negotiated with the manufacturers. The products' price is such that providers' losses when they deliver CAR-T in the inpatient setting cannot be offset by increased efficiencies in the delivery of care. Clarity about product-based cost reimbursement will allow more providers to begin or continue offering CAR-T to Medicare beneficiaries. Separation of the product reimbursement from clinical care will prevent distortion of the assigned MS-DRG's

representation of the cost of clinical services associated with the administration of CAR-T and will not temporarily inflate the MS-DRG 016 payment rate.

We acknowledge the sensitivity associated with the appearance of support for current drug pricing and ASP-based payment solutions. We first wish to clarify that the ASBMT does not endorse the price of these therapies; we share CMS's concerns regarding the sustainability of the Medicare system given increasing cost drivers. Additionally, we want to clarify that while we are seeking site-neutral reimbursement mechanisms, we are not requesting ASP+6%, as utilized in the Part B system. Our members and providers are seeking to be appropriately reimbursed for product costs based on the average sales price alone.

During discussions of this potential solution with other partner organizations and stakeholders, concerns were raised that the use of an ASP- or invoice-based payment system would incentivize drug prices to increase further. We understand the concern but note that it assumes that the current bundled payment system should have the opposite effect – i.e., if an ASP-based product mechanism causes excessive price points, then bundling these services into a MS-DRG without providing add-on or pass-through payment would drive drug prices *down*.

This fiscal year has, in fact, demonstrated that this opposing hypothesis is inaccurate. Manufacturers were aware that providers would be largely limited to inpatient provision of CAR-T due to safety concerns, would be reimbursed on a non-specific MS-DRG basis, and would not have NTAP during FY 2018. Yet, CAR-T prices remain at \$373,000 for both products approved for DLBCL. *The cost-containment incentivization of the MS-DRG system did not create a discernible downward effect on the cost of CAR-T products; it only created a situation in which providers became the default group to shoulder the financial burden associated with this therapy.*

ASBMT's member providers have diligently and hopefully participated in the clinical trials that brought these ground-breaking therapies to the market. To be restricted on their use due to a financial liability beyond providers' prediction or control is heart-rending for many. Thus, while ASP may have multiple political connotations, the acquisition cost's impact upon cellular programs is immutable and has driven us to seek a solution that neutralizes this portion of provider liability.

#### Rationale for the Use of MS-DRG 016

Given that these therapies are new and there is a lack of utilization and cost data for CAR-T cases, we agree with CMS's proposal to assign CAR-T cases to MS-DRG 016. We ask, however, that CMS make this assignment *only for the next two to three fiscal years* and use the resulting data to assess payment policies. The ASBMT believes that data received during this time will indicate that the most appropriate long-term solution is the establishment of one or more separate CAR-T MS-DRGs.

Autologous cell transplantation (AutoHCT) and CAR-T serve very different clinical purposes. AutoHCT introduces minimally manipulated autologous cells to reestablish a patient's hematopoietic system after ablative chemotherapy. CAR-T is a genetically modified autologous product that is infused to directly attack cancer cells within a patient's body. AutoHCT patients



must be monitored closely for infections during the immune reconstitution period, but rarely have complications on the scale of those associated with CAR-T. Notwithstanding the clear clinical differences between the two therapies, we believe that it is preferable for CAR-T cases to be assigned to a single, pre-MDC type MS-DRG than for them to continue grouping into multiple DRGs, as is currently the case. However, it should be noted that assignment to MS-DRG 016 is unlikely to cover patient care costs exclusive of the CAR-T product cost, even on average, due to the specific disease indications and severity associated with CAR-T. However, *assuming the product costs are separately paid*, the current outlier methodology will adequately address CAR-T cases with extraordinarily high care costs stemming from post-infusion complications (i.e., ICU stays, increased overall lengths of stay, additional diagnostic tests, and other therapeutic services).

**The ASBMT believes that one or more new MS-DRGs for CAR-T will be necessary over time.** To support analysis of the impact of assigning CAR-T cases to MS-DRG 016 on payment for both CAR-T and AutoHCT cases, we ask CMS to provide separate data on the CAR-T cases within MS-DRG 016 in each FY Proposed Rule.

**g. Policy Benefits Associated with Product Acquisition Cost Pass-through Payment**

We recognize that our request to CMS has limited precedent within the IPPS system. The ASBMT believes, however, that several important policy arguments support our request, which we make on behalf of our members and the patients they serve.

Specifically, by implementing our proposal, CMS would:

- Be able to swiftly recognize any cost savings achieved through drug pricing initiatives or market competition forces; the agency would not overpay for one or more fiscal years as it might with an MS-DRG that includes product price, since those data lag behind market evolution.
- Be able to separately and clearly collect data on the products and costs associated with clinical care in both care settings. The agency could study variances in costs of care, complications, and outcomes associated with the specific products over time.
- Be able to easily separate payment for the product from payment for clinical care if the Agency engages in outcomes-based purchasing contracts for CAR-T.
- Avoid potential overpayment based on standard wage index, disproportionate share, and indirect medical education (IME) adjustments that would be driven by embedding the product costs into the MS-DRG. The agency would also avoid inadvertently disadvantaging hospitals with a low wage index due to standard adjustments.
- Neutralize financial incentives to provide CAR-T in the outpatient setting before it is clinically appropriate, which currently stems from the agency's OPPS reimbursement rate of ASP+6%.
- Avoid spending a disproportionate amount of the outlier pool on product-related costs; the agency would ensure that only cases in which patients needed intensive-level clinical care receive outlier dollars.

- Set a precedent for price transparency for new cell and gene therapies; the agency’s use of new revenue codes would enable consistent tracking of current and future therapies for use in health economic studies.
- Align with payer and patient advocacy groups’ desire for standard charge transparency. The agency would allow hospitals to create a charge based on the acquisition cost itself, rather than a mark-up designed to ensure that acquisition costs flow through to NTAP and outlier calculations.
- Align with other payers’ policies for CAR-T; commercial payers, including Medicare Advantage plans and several Medicaid providers (Massachusetts, New York and Washington) already reimburse hospitals on a pass-through basis for the product cost and provide a separate payment for clinical services associated with the inpatient stay.

#### **h. Pass-Through Payment for CAR-T is a Logical Outgrowth of the Proposed Rule**

The ASBMT’s proposed pass-through payment for CAR-T cells can be adopted in the Final Rule without additional comment, since it is a logical outgrowth of the Proposed Rule. If a Final Rule resolves issues within the scope of the original proposal scheme and the comments received during the rule-making process, then it is a logical outgrowth of the Proposed Rule and a new period of notice and comment is not required.

More specifically, the preamble of the Proposed Rule states:<sup>18</sup>

We are inviting public comments on our proposed approach of assigning ICD–10–PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS–DRG 016 for FY 2019. **We also are inviting public comments on alternative approaches, including in the context of the pending KYMRIA® and YESCARTA™ new technology add-on payment applications, and the most appropriate way to establish payment for FY 2019 under any alternative approaches.** Such payment alternatives may include using a CCR of 1.0 for charges associated with ICD–10–PCS procedure codes XW033C3 and XW043C3, given that many public inquirers believed that hospitals would be unlikely to set charges different from YESCARTA™ CAR T-cell therapy drugs, as discussed further in section II.A.4.g.2. of the Addendum of this proposed rule. These payment alternatives, including payment under any potential new MS–DRG, also could take into account an appropriate portion of the average sales price (ASP) for these drugs, including in the context of the pending new technology add-on payment applications.

CMS solicited comments on “*any alternative approaches*” to making payment for CAR-T cells. CMS proposed using a CCR of 1.0 for CAR-T cases to reflect the true cost of these cells.<sup>[1]</sup>

<sup>18</sup> Fed. Reg. May 7, 2018. Page 20189.

<sup>[1]</sup> See, *American Trucking Assoc., Inc. v Fed. Motor Carrier Safety Admin.*, 2013 WL 3956992 at \*7 (DC Cir Aug. 2, 2013) (finding that a final rule imposing a off-duty break of at least 30 minutes to short haul drivers was a logical outgrowth of the proposed rule, which would have require short-haul drivers to comply with a broader range of regulations which included off-duty breaks); *In re Polar Bear Endangered Species Act Listing and Section 4(D) Rule Litigation - MDL No. 1993, Safari Club International, et al. v. Jewell*, 720 F.3d 354, 363 (D.C. Cir. 2013) (finding

The ASBMT's proposal to establish a pass-through payment for CAR-T cells falls within the scope of CMS's solicitation of comments on "*any alternative approaches*" to its proposals to establish a new MS-DRG or use a CCR of 1.0 for CAR-T NTAP and outlier payments. The intent of both CMS proposals is to ensure that IPPS payments for CAR-T cases encompass the actual cost of CAR-T cells to IPPS hospitals.

The intent of our proposal for a pass-through payment for CAR-T cells is the same as that of CMS's proposals and would create similar results. Comments proposing a different means to achieve the same goal are, therefore, a logical outgrowth of the Proposed Rule.

#### **i. Implementation Details for Separate Product Acquisition Payment**

The ASBMT believes the simplest and most straightforward approach to provide a separate add-on payment is for CMS to use its existing infrastructure for providing separate payment for hemophilia blood clotting factors based on the ASP. CMS currently requires hospitals to report line item HCPCS detail for blood clotting factors on inpatient claims. CMS uses the HCPCS code and the presence of hemophilia diagnosis codes on inpatient claims to make an ASP-based add-on payment to the MS-DRG.

If CMS were to follow this model for CAR-T, as we strongly recommend, it would instruct hospitals to report the appropriate CAR-T HCPCS code as a line item charge on the inpatient claim. CMS would replicate the blood clotting factor's claims processing logic for CAR-T by looking to the ASP file for the applicable payment for the CAR-T product when it appears on an inpatient claim along with one of the two ICD-10-PCS codes for CAR-T administration.

For the outlier calculation, the CAR-T line item charge would be backed out of the total covered charges on the inpatient claim before application of the overall CCR and determination of whether the calculated costs exceed the outlier threshold. After this outlier calculation is made, the ASP-based add-on payment for the CAR-T product would be added back to the MS-DRG and any outlier payment, if applicable. We refer CMS to the Medicare Claims Processing Manual, Chapter 3 (Inpatient Hospital Billing), Section 20.7.3 for details on CMS' current process for blood clotting factors.

By requiring hospitals to report the detailed charge for CAR-T on the inpatient claim and instructing hospitals to separately report their CAR-T expense and revenue in their cost reports, CMS could assess actual hospital cost for both inpatients and outpatient provision of CAR-T, as well as the impact on the manufacturer-reported ASP over time. When claims were paper-based,

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that the plaintiffs should have anticipated the agency's final course in light of the initial notice, rendering the final rule a logical outgrowth of its notice) (internal quotations omitted); *United Steelworkers of America, etc. v Marshall*, 647 F2d 1189 (D.C. Cir. 1980), cert. den. 453 US 913 (1981) (upholding a final workplace safety rule limiting employee exposure to airborne lead in concentrations greater than 50 micrograms per cubic meter and have different phase in periods for different industries, although OSHA had proposed to lower the permissible exposure level to 100 micrograms per cubic meter for all industries). See also, *Spartan Radiocasting Co. v Federal Communications Comm'n.*, 619 F2d 314 (4th Cir. 1980) (holding that a NPRM must be sufficient to fairly apprise interested parties of the issue involved but need not specify every precise proposal that the agency may ultimately adopt as a rule).

it made sense not to obtain drug details from an administrative burden and claims processing perspective. Presently, the use of electronic claims eliminates these concerns; many hospitals report drug HCPCS detail on inpatient claims under revenue code 0636 today, even though it is neither required nor expected.

Since ASP reflects all sales for all drugs in both care settings, it updates naturally to reflect sales and/or discounts if any are provided. ASP is an expedient way to address charge compression issues and effectively implement pass-through payment. For this reason, the ASBMT recommends its use for FY 2019 as a temporary proxy for actual acquisition cost, until CMS has more data on actual costs.

Our recommendation is based on our understanding of the work being undertaken by the National Uniform Billing Committee (NUBC) right now. Specifically, we understand the NUBC is considering the creation of a new value code to report product acquisition costs on the inpatient claim. If this is implemented, CMS could instruct hospitals to report the actual acquisition cost on each CAR-T claim in addition to the line item detail charge for the CAR-T product. With this method, CMS would substitute the CAR-T acquisition cost reported by the hospital in place of the line item charge, neutralizing any mark-up the hospital may have made. This also has the added benefit of allowing CMS to immediately see the actual acquisition cost and the billed charge on each claim.

A new value code from NUBC is not certain to be introduced by October 1, 2018, however, and it will take time for CMS, other payers, and hospitals to implement the new code when it has been approved. For this reason, we are unsure whether this option can be implemented for FY 2019. CMS may wish to transition to this option for FY 2020 and beyond if the agency agrees that full insight into acquisition cost for CAR-T is beneficial.

#### **j. Ineffective Proposed Solutions**

The ASBMT notes that it was one of the organizational commenters that requested the use of CCR of 1.0 and creation of a new MS-DRG in letters submitted to CMS in Fall 2017. We suggested the idea of a CCR of 1.0 to prevent charge compression for cases in FY 2018 and to provide CMS actual invoice data to assist with FY 2019 rate-setting policies. At the time, these recommendations were identified as potential short-term solutions for the expected FY 2019 and future IPPS reimbursement issues.

Since that time, our members and their programs began providing CAR-T to Medicare beneficiaries and have gained a better understanding of the therapy's true financial impact and its concomitant challenges. This has presented us with an opportunity for more detailed analysis of the initial proposals. As a result, the ASBMT's preferred solution has evolved and now focuses on addressing charge compression through full ASP or acquisition-based reimbursement of the product cost separate from the patient care costs.

Despite this preference, we believe it is important to detail our thinking about the alternatives we carefully evaluated in terms of fiscal impact and meeting our overall objectives. The solutions

described below are less effective than our preferred solution. We explain our concerns and issues with each to help CMS gain insight into our perspective.

### 1) Assignment of cases to MS-DRG 016 and application of NTAP

We modeled the effect of assignment to MS-DRG 016, along with NTAP eligibility, for a variety of hospitals with diverse mark-up practices. ***While almost every case qualified for outlier payment, predicted losses for every case still ranged from \$60,000 to more than \$300,000.*** This level of loss is similar to what providers are currently experiencing and is therefore unacceptable to the provider community.

NTAP payments are intended to reflect the marginal difference in the cost of cases that use new technologies, while outlier payments are intended to recognize cases that fall at the extreme high end of a range of costs. In the case of CAR-T therapy, a patient is admitted solely for the planned administration of CAR-T therapy and would not otherwise be hospitalized with curative intent; therefore, it is necessary from a policy perspective to recognize the *full cost* of the new service, rather than just a marginal difference.

Additionally, while outlier payment is available to PPS hospitals, the standard adjustments that the IPPS uses to recognize variation in costs of care are not designed to address this situation. Under the current IPPS methodology, all CAR-T cases are likely to qualify for outlier payments, not just the most expensive cases. This indicates that the base payment remains wholly inaccurate and inadequate. We are also concerned with the impact of paying outliers on virtually all CAR-T cases on future outlier thresholds that are applicable to all MS-DRG cases.

NTAP and outlier payments are strongly dependent on product mark-up. We note that, due to the extremely high product cost, some hospitals are likely to have a much lower mark-up of the CAR-T product than the average mark-up applied to other drugs. As CMS is aware, providers vary in their mark-up practices for drugs, devices, supplies, and all other services. This variation fundamentally impacts Medicare's estimation of provider cost, as well as a provider's ability to avail itself to an outlier payment.

Under current formulas, hospitals would need to apply the standard drug mark-up to CAR-T, resulting in a very high gross charge, just to ensure that some portion of the costs are recognized in CMS' calculation and final payment. Even then, providers would still face the unsustainable losses cited above.

Approving an NTAP under the current formula would perpetuate issues with charge compression and encourage hospitals to use mark-ups based on their overall CCR. When applied to CAR-T, this would result in the already high product costs being billed as individual charges of more than \$1 million dollars. This puts providers in an untenable position and some are unwilling to suffer the negative media attention such charges would likely invite.

Continuing a system that requires providers to mark-up already high invoices in order to attempt to achieve partial payment exacerbates problems with price transparency. Given CMS' comments on price transparency in this Proposed Rule, the ASBMT does not believe CMS



wishes to perpetuate a structure that incentivizes mark-ups. We encourage CMS to finalize a payment policy that fairly reimburses CAR-T expenses without the concomitant pricing and charge compression issues that are imposed by current IPPS reimbursement structures. Please see our comments on posting standard charges later in this document.

## 2) Addressing Charge Compression through a CCR of 1.0

The ASBMT evaluated the application of a CCR of 1.0 to the CAR-T product in addition to the prior potential solution of case assignment to MS-DRG 016 and use of NTAP. ***While this option reduces variability in final payment based on mark-up practices, losses are still too high at approximately \$60,000 per case.*** Additionally, if CMS were to apply the CCR of 1.0 to the line item billed charge for CAR-T, it could result in significant overpayments to some providers due to the variability in provider mark-up practices discussed earlier.

## 3) Creation of a New MS-DRG

Based on modeling, the creation of a new MS-DRG would need to include almost all (90% or more) of the product cost in the base weight to pay appropriately for CAR-T cases. ***However, this creates inequity among treatment centers and increases the potential for underpayment and overpayment by CMS based on the inclusion of the drug costs in standard adjustments.***

Under the IPPS, the base MS-DRG payment amount is subject to numerous adjustments, including adjustments to reflect variation in labor costs, increased costs incurred by serving as a site for graduate medical education and those from caring for low-income patients. The labor cost adjustment is applied to a labor-related share, which depends on the wage index for the area in which the hospital is located. This adjustment can increase or decrease payments from the base amount. The labor cost adjustment is applied to 68.3% of the base payment amount in areas with a wage index of more than 1.0, and 62% in areas with a wage index of less than or equal to 1.0. The indirect medical education (IME) and disproportionate share hospital (DSH) adjustments also increase payments.

These adjustments are determined based on costs associated with the full range of cases paid for under the IPPS. They involve patients who have different and varied diagnoses and who may receive diverse regimens and quantities of care. While some of those cases may include relatively high-cost therapies (i.e., drugs or devices) that have fixed costs, they also typically include a range of other items and services that are likely to be affected by the adjustment factors, such as labor costs.

In contrast to the average IPPS cases, the cost of CAR-T cases is dominated by a single item: the CAR-T product. The product cost is expected to account for more than 90% of the full cost of the CAR-T case. Applying adjustments derived for cases with very different cost structures may inappropriately underpay or overpay CAR-T cases when the product costs are incorporated into the MS-DRG base payment amount.

For example, if the CAR-T product accounts for 90% of the case's cost, it is impossible for labor costs to simultaneously represent more than 60% of these same costs. Applying the labor

adjustment to costs that are primarily fixed will consistently produce inappropriate payment rates. While we recognize that the IPPS methodology does not intend to pay the full cost of any particular case precisely, the impact of the adjustments is exaggerated beyond the usual effect due to the magnitude of the CAR-T case costs. Furthermore, including CAR-T product costs in the MS-DRG has the potential to significantly impact the wage portion and other IPPS factors applicable to all hospitals over time.

#### **k. New Technology Add-on Payment Requests**

The ASBMT believes that the CAR-T products that applied for NTAP status meet each of the criteria. However, due to the nature of our comments, we prefer CMS to address the cost discrepancy of this new technology through a mechanism other than NTAP. We support CMS's assessment of "*substantial equivalence*" for the two CAR-T applicants.

#### **l. Considerations for Future MS-DRG Rate-Setting: FY 2020 –FY 2023**

Ideally, as discussed elsewhere in this comment letter, CMS will decide to pay the ASP for the product as an add-on to an MS-DRG payment designated for CAR-T patient care costs. However, if CMS wants to progress towards transparency regarding CAR-T prices, actual acquisition cost may be the ultimate objective for individual case payment to hospitals and for use in future rate setting. If the NUBC approves a value code to report CAR-T acquisition costs on claims, CMS will still need to allow implementation time for both hospitals and its own claims processing systems. Therefore, CMS could consider using the ASP as a stepping stone to obtaining actual acquisition cost in FY 2020. This would enable CMS to track individual hospital cost and gain visibility into how actual costs are reflected in the ASP data reported by the manufacturers.

Due to the unique considerations associated with CAR-T provision, the ASBMT is also concerned about future MS-DRG rate setting for CAR-T cases. The proposal to use a CCR of 1.0 (i.e., ASP) is intended to neutralize problems with charge compression that will occur on CAR-T drugs without remediation from CMS. But, the remediation options that CMS is considering *must* begin in FY 2019 and continue into the future. Therefore, to continue avoiding charge compression, CMS must implement changes for FY2019 to isolate the costs and revenue for CAR-T in the cost report.

CMS should implement the changes discussed below because the relatively small number of CAR-T cases still has the potential to rapidly change the pharmacy cost group CCR due to the products' extraordinary expense. This would have the impact of increasing payment for pharmacy in all MS-DRGs rather than focusing the payment solely for CAR-T cases. Therefore, ASBMT asks CMS to implement a number of changes, beginning with support of proposals at the NUBC for new revenue codes for CAR-T and other future genetically engineered cell therapy products and services. This is very important to implement in order to isolate the high costs of these products on claims.

We also ask that CMS establish a new dedicated cost center in cost reports for CAR-T and other genetically engineered cell therapy products to be matched to the revenue reported with the new

NUBC revenue code. This new cost center would be separate from the pharmacy cost center in order to prevent the expense and revenue from being aggregated with all other drugs and spread throughout all MS-DRGs in the usual rate-setting process.

Finally, we ask that CMS create a new dedicated national cost center for cell and gene therapies for use in future MS-DRG rate setting. Without implementing each of these steps concurrently, CMS risks increasing all other MS-DRGs with CAR-T expense if its expenses and revenues are aggregated with all other drugs.

### **III. Align Payment for HCT with Other Organ Transplants**

The ASBMT appreciates the focus CMS has recently placed on improving transplant reimbursement in both the inpatient and outpatient settings. CMS has implemented changes that facilitate better provider reporting of data and improved use of information for rate-setting. These improvements include the creation of a dedicated revenue code (0815), a dedicated cost center (77) and an outpatient edit that requires the presence of the donor search and cell acquisition revenue code (0815) along with as the outpatient transplant procedure code (38240). While we commend CMS for making these changes, the ASBMT remains concerned that inpatient Medicare reimbursement for MS-DRG 014 for allogeneic bone marrow, cord blood, and peripheral blood stem cell transplants (AlloHCT) remains too low. Current reimbursement levels do not adequately cover the actual cost of the care provided to these beneficiaries, including donor acquisition costs.

Due to strong federal commitment to the National Marrow Donor Program (NMDP) and the government's interest in continuing to eliminate barriers to access, we ask that CMS follow recommendations of the Advisory Council on Blood Stem Cell Transplantation and adopt a policy similar to what is used for reimbursing hospitals when living donors donate a kidney (42 C.F.R. § 412.100) – that hospitals may be paid a separate amount for their cost to acquire the cells used in transplant apart from the MS-DRG amount. In addition to the hundreds of letters from transplant centers, physicians, and patients submitted to CMS on this issue, Members of Congress have also signaled, through H.R. 4215 (the Protect Access to Cellular Therapies Act' [PACT] Act) that there is a need to address this problem. We ask CMS to work directly with Congress to pass the PACT Act, so that it can take effect for Fiscal Year 2019. PACT will ensure that hospitals are paid a separate amount for their cost to acquire the cells used in transplant, as well as the MS-DRG amount.

We also request that CMS continue to do what it can from a regulatory and claims instruction and processing perspective so the Agency has the most accurate and complete data to use in future rule-making and rate-setting. To that end, we have a number of specific requests, which are outlined as follows.

First, we strongly urge CMS to implement an edit in the inpatient Medicare Code Editor (MCE) that requires the presence of revenue code 0815 and one of the transplant ICD-10-PCS codes. CMS created a similar edit for the outpatient code editor (OCE) and the ASBMT has not heard any issues or concerns from providers regarding this edit. In fact, we believe this edit is a beneficial safeguard against incorrectly coded claims being submitted to CMS, paid as HCT and

inappropriately included in rate-setting. Our fundamental belief is that CMS should use only correctly coded claims as often as possible; for allogeneic HCT, accurate claims are those with both the revenue code and the transplant procedure code.

Second, in addition to creating the edit being requested, the ASBMT requests that for FY 2019 rate-setting, CMS use only correctly coded claims for FY 2019 MS-DRG 014 rate-setting (i.e., claims with 0815 and one of the transplant procedure codes associated with a related or unrelated donor as reported through the seventh digit of the code). This will ensure that FY 2019 rate-setting for MS-DRG 014 for allogeneic stem cell transplant includes only claims on which providers reported donor search and cell acquisition costs.

Third, we believe provider reporting would improve significantly if CMS more explicitly described its decisions and instructions in the final rule. For example, we believe CMS should explicitly clarify the intent and appropriate use of revenue code 0815 and cost center 77. Neither the revenue code nor the cost center appears in CMS' IPPS revenue code cross-walk table, which is problematic when providers wish to reference them and/or conduct educational efforts. An additional level of transparency will facilitate transplant providers knowledge and understanding about the new cost center and revenue code.

Pursuant to cost report line 77, we ask that CMS issue explicit instructions about how hospitals should capture their revenues and expenses, since providers are largely either unaware of cost report line 77 or unsure how to implement it. As it is a purchased service from the NMDP, and individual invoices for these services are sent to the hospital, it is relatively easy to identify donor expense for unrelated donor cells. It is much harder to isolate the dollars associated with related donors (siblings, parents, children) that are evaluated in-house. Given that there is little to no guidance on how costs should be aggregated for related donors who receive services on behalf of the transplant patient directly from transplant centers, we urge CMS to release very clear guidance on how to capture these services.

Finally, we ask CMS to reconcile a coverage discrepancy in the MCE. CMS began covering Multiple Myeloma under Coverage with Evidence Development (CED) on January 1, 2016 (<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-MM.html>), yet several of the applicable procedure codes are listed as “non-covered” on pages 283-284 of the MCE, including Multiple Myeloma diagnosis codes 90.00 and 90.01. It is possible that there is no error in the actual software and that the error exists solely in the MCE documentation, but we respectfully request CMS review this and swiftly make any necessary corrections so provider claims are not inappropriately denied.

#### **IV. Public Reporting of Standard Charges**

The ASBMT appreciates CMS' desire to further the conversation on price transparency and its request for comments on its proposals and questions concerning insurance and patient financial liability under current insurance structures. We share CMS' desire to advance patients' understanding of their financial obligations with regard to both covered and non-covered services. Our members are very experienced with financial counseling related to cell

transplantation and are applying this same experience to financial counseling of CAR-T patients. It with this understanding and experience that we offer the following comments.

We believe that requiring hospitals to publish a list of standard charges will not contribute or advance any of the objectives CMS seeks regarding price transparency. Rather, this will serve to confuse and potentially frighten patients who do not understand that their out-of-pocket responsibility often has no relationship to the published charges. We ask CMS to retain the current guideline, under which hospitals have a choice to make public a list of their standard charges or provide contact information, allowing patients (and prospective patients) to inquire about and receive a customized analysis of their financial liability. This flexibility is very important, particularly given that specific requirements regarding price transparency are dictated by individual state laws. Most states already require some method of price transparency. The ASBMT does not support the added administrative burden it would take to sort out differences between state and federal requirements should CMS become more prescriptive in this regard.

We are concerned that requiring hospitals to publicly post these charges may result in additional barriers to patient access. Looking up charges on a list will not allow patients to understand the relationship between charges and costs or between charges and beneficiary cost-sharing. For example, there is very limited usefulness in posting that the price of a CAR-T product is \$373,000, when the Medicare Part A patient deductible limits beneficiary cost-sharing to \$1,340 per benefit period. Posting of charges may cause patients to refrain from seeking the therapies and treatments they need for fear of the expense.

## **V. Conclusion**

The ASBMT aims to fairly balance the concerns of our membership against the realities of CMS authority and the expressed priorities of the Administration. We feel that our proposed changes for reimbursement of CAR-T and HCT are in keeping with the best interests of the beneficiary population and with the larger political discussion around reimbursement and cost transparency. We ask that CMS implement the changes discussed in this letter and we welcome the opportunity for dialogue with the Agency about these matters.

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