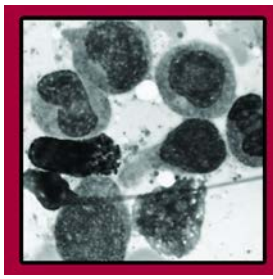

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November 1, 2017

Elizabeth Richter
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard,
Baltimore, MD 21244-1850.

CC: Demetrios Kouzoukas; Carol Blackford; Ing Jye Cheng; Donald Thompson; Michelle Hudson; Marilu Hue; Patricia Brooks

RE: Request for New MS-DRGs for CAR-T Therapy for FY 2019

Ms. Richter:

The American Society for Blood and Marrow Transplantation (ASBMT) is an international 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. ASBMT is dedicated to improving the application and success of hematopoietic cell transplants and/or other cellular therapies, such as CAR-T.

Hematopoietic cell transplantation (HCT) is a medical sub-specialty comprised of physicians with Board Certifications in Internal Medicine, Medical Oncology, Pediatrics, Hematology and/or Immunology. CMS recognized the unique role and qualifications of HCT physicians by designating a unique code for Hematopoietic Cell Transplant and Cell Therapy (HCTCT) physicians in November 2016.[1] Due to their unique clinical expertise and training, ASBMT member clinicians and cellular therapy programs will be the primary individuals and teams initially providing Chimeric Antigen Receptor T Cell Therapy (CAR-T) to patients in need of treatment. We anticipate that CAR-T is the first of many engineered cellular therapies to be approved in the coming decade.

This class of therapies will require unique reimbursement considerations given their newness relative to the long-standing Medicare reimbursement systems and their anticipated costs to providers as part of providing quality care. We concur with the expert commentary labeling

[1] CMS MLN Matters MM957

cellular therapies as the key breakthrough therapy of the 21st Century, as discussed at the July 13, 2017 FDA Oncology Drugs Advisory Committee.[2] Due to the involvement of our membership and the coming wave of innovation that these cellular therapies represent, the ASBMT is keenly interested in how to improve Medicare's long-standing reimbursement models so they can be applied fairly and adequately to these technologies on behalf of our members.

Summary of Request

Given the recent approvals of the Novartis CAR-T product, Kymriah, and Kite/Gilead's product, Yescarta, ASBMT is requesting that CMS exercise its authority to create new MS-DRGs for the provision of CAR-T therapy in FY2019. This request is in addition to ASBMT's request to CMMI to invoke its innovation authority to provide immediate reimbursement relief for FY 2018 to hospitals providing CAR-T (see separate attached letter). We believe both approaches, applied in tandem, are necessary to preserve beneficiary access to this therapy.

Products and Timeline

There are two CAR-T products which have received FDA approval in the 2017 calendar year. Novartis's Kymriah was approved on August 30, 2017 for B-cell acute lymphoblastic leukemia (ALL) in patients up to age 25. The Gilead/Kite product, Yescarta, was approved on October 18, 2017. Yescarta is indicated for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. The sub-types of lymphoma indicated for Yescarta are most prevalent in individuals over the age of 60.

Estimates of Treated Population

Manufacturers have noted that for the B-cell Lymphoma group of indications, approximately half of the estimated 7,500 patients treated per year may be in the Medicare beneficiary population. While this is not high volume in comparison with some inpatient procedures, CMS would have approximately 3,000 claims per year to utilize in rate-setting. As additional indications are approved, these numbers will likely grow.

Care Pathway Overview

A simple explanation of CAR-T is the following, as described by the National Institutes of Health:

"As its name implies, the backbone of CAR-T-cell therapy is T cells, which are often called the workhorses of the immune system because of their critical role in orchestrating the immune response and killing cells infected by pathogens. The therapy requires drawing blood from

[2] FDA ODAC Meeting, July 13, 2017

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patients and separating out the T cells. Next, using a disarmed virus, the T cells are genetically engineered to produce receptors on their surface called chimeric antigen receptors, or CARs."[3]

From the patient treatment perspective, the process is as follows:

1) Patient is diagnosed with qualifying condition and is referred to treatment center.
2) Patient travels to treatment center for initial consultation and treatment planning; patient may return home or remains at treatment center for on-going treatment of disease.
3) Patient returns to treatment center to have cells collected through a process called autologous apheresis or leukapheresis; this may be conducted in either the inpatient or outpatient setting.
4) The hospital places an order for production and ships patient cells to manufacturer; patient may return home during the production process.
5) Up until infusion of the CAR-T product, the patient may be receiving chemotherapy to control disease progression. The routine chemotherapy treatments may be administered inpatient or outpatient, depending on patient need and medical status.
6) Patient returns to the treatment center after being notified of successful manufacturing.
7) Patient receives preparatory lymphodepleting chemotherapy ("priming") in either the inpatient or outpatient setting. If inpatient, this may or may not be a separate stay from the infusion episode of care.
8) ***Patient admitted to hospital for CAR-T infusion.*** *The patient remains in the hospital for a minimum of 7-10+ days, depending on the patient's individual response and until the treating physician team feels confident that the patient is not experiencing moderate to severe complications. Provision of CAR-T in the outpatient setting will likely be available for specific subtypes of patients at a limited number of facilities, but will be uncommon (10% of cases) in the immediate post-approval period.*
9) For approximately 15-30% of patients of patients, moderate to severe complications will result in **staying in the hospital for several additional weeks** as symptoms are being treated. Cytokine Release Syndrome (CRS) symptoms will begin appearing in affected individuals within 2-7 days after infusion with the product and neurotoxicity symptoms typically appear within 5-7 days of infusion.
10) Patient remains nearby the treatment center for an additional 2-4 weeks post-discharge for monitoring by the clinical team.
11) Patient returns home for on-going monitoring with local physician.

Complications

After infusion of the CAR-T product, patients have a moderate risk of complications that require additional inpatient care and support. Cytokine Release Syndrome (CRS) is a group of systemic reactions due to the high volume of cytokines released from cells targeted by the engineered T-

[3]

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cells; symptoms include fever, fatigue, and pulmonary and cardiac changes.[4][5] In addition to CRS, patients may experience neurotoxicity of varying degrees ranging from mild confusion to the inability to speak and unconsciousness. Uniform systems of grading these complications are being refined and complications vary by product and treatment population, but it is expected that somewhere between 15-30% of patients will experience Grades 3-4 CRS and/or neurotoxicity.

In Kite Pharma's Zuma-1 KTE-C19 study, 43% of patients experienced complications severe enough to warrant aggressive treatment. Clinical teams use various combinations of corticosteroids, supportive interventions and immunosuppressive medications, such as Tocilizumab, to control and reverse symptoms. Patients experiencing complications are frequently moved from their regular bed location to an Intensive Care Unit at the first sign of these symptoms and are treated there until symptoms abate. These complication-driven therapeutic interventions will clearly add additional costs to the overall inpatient episode and are not typical expenses for patients being treated for lymphoma; these costs are thus not captured in historical claims data utilized to set future payment rates, including the FY 2019 lymphoma MS-DRG rates.

Limited Facilities for CAR-T Provision

Manufacturers have stated publicly[6] that only a very limited number of facilities – likely between 10-30 for the first year and up to 90 by the end of year 3 – will be approved to administer one or both of the commercially approved CAR-T products.[7] This means that patients from the entire United States will be directed to a relatively small number of facilities to receive treatment. Given the intensive requirements needed for proper patient management and monitoring, it is appropriate that only a limited number of facilities will offer this new therapy at the outset.

However, this also means that this limited group of facilities will experience concentrated effects of the known reimbursement deficits. If even a small percentage of these facilities decide that the financial burden of treating Medicare patients with CAR-T is more than they can sustain financially, access could become a serious problem for patients seeking care. Therefore, we ask CMS to carefully examine the access implications that its current reimbursement policies will likely have on the facilities that will be administering this new therapy.

Inpatient Care Setting for CAR-T Therapy Creates Reimbursement Problems

A poll of ASBMT member experts – physicians who deliver CAR-T to patients – indicates that the vast majority of clinical teams are planning to keep all of their patients in the inpatient setting for at least 7 days after infusion to closely monitor for complications. CAR-T is not presently

[4] Cytokine Release Syndrome: Overview and Nursing Implications
[5] Neelapu et al, *Nature Reviews Clinical Oncology*, Fall 2017, publication in press
[6] FDA ODAC Novartis Hearing, July 12, 2017; Kite Pharma 2nd Quarter Earnings Call, August 8, 2017
[7] Kymriah Treatment Sites, September 3, 2017

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eligible for a new technology add-on payment (NTAP) due to a misalignment of product approval dates and the annual cycle timeframe utilized by CMS. This leaves the MS-DRG payment along with some outlier payment possibility as the sole source of reimbursement for this expensive new therapy until at least October 1, 2018. As outlined previously, CAR-T provision will be predominantly in the inpatient setting, for the immediate post-approval timeframe. Additionally, both product acquisition and post-treatment complication costs are much different cost drivers for CAR-T cases than with typical lymphoma cases, and will be concentrated within the inpatient CAR-T infusion stay. As it currently stands, CAR-T inpatient stays will be assigned to one of a few possible MS-DRGs, all of which have payment rates that will be grossly inadequate to cover provider costs for this breakthrough drug and its administration.

Problematic Acquisition Costs and FY2018 MS-DRG Groupings

Novartis has announced the Kymriah will be priced at $475,000[8] and Gilead-Kite has set a price of $373,000[9]. This pricing is specific to the engineered cells (i.e., the biologic drug product) itself and does not include any other patient care provision and expense. Other costs the facility incurs include inpatient nursing, infusion administration and treatment costs for post-infusion complications, including the use of high cost medications and specialized care from teams outside of cellular therapy – pulmonology, cardiology, intensive care and neurology.

Given the unique clinical aspects of these cases along with the very high CAR-T product cost, we believe it is imperative for CMS to use a pre-MDC MS-DRG assignment mechanism for CAR-T cases. This would allow both CMS and the provider community to know the reimbursement structure in advance for these clinically complex and resource intensive cases and allow both groups to analyze claims data in the future without having dilution by other types of cases. If CMS does not create new MS-DRGs for CAR-T for FY 2019, we believe the most likely medical MS-DRG assignments for CAR-T cases (i.e. subtypes of non-Hodgkin lymphoma with no accompanying surgical procedure) are those listed below.

Table 1: Potential MS-DRG for CAR-T Inpatient Stays Based on Current Grouper Logic

MS-DRG	MDC	Type	Title	Weights	Approximate Base Reimbursement	Geo Mean LOS
840	17	MED	LYMPHOMA & NON-ACUTE LEUKEMIA W MCC	3.0786	$16,736	7
841	17	MED	LYMPHOMA & NON-ACUTE LEUKEMIA W CC	1.6201	$8,807	4.3
842	17	MED	LYMPHOMA & NON-ACUTE LEUKEMIA W/O CC/MCC	1.1241	$6,110	2.9

[8] Bloomberg, August 31, 2017
[9] Reuters, October 18, 2017

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MS-DRG 840 has the highest relative weight - 3.6284 - and a base reimbursement of approximately $16,736. Separate from the cost of the product, the average length of stay for Medicare beneficiaries receiving Yescarta will likely deviate substantially from the range of ALOS numbers associated with these MS-DRGs. As CMS notes in the Agency's NTAP comments in the IPPS FY18 Proposed Rule, Kite Pharma's application supplied information that indicated a median stay of 15 days.

As noted earlier, the subset of patients that develop one of known potential post-infusion complications, including CRS and/or treatment-associated neurotoxicity, will likely require hospitalization until symptoms fully resolve – potentially for up to 2-3 additional weeks. Hospital acquisition costs of Tocilizumab, used to treat CRS, were reported by member pharmacists to be $5,000-$10,000 per therapeutic dose, depending on the patient, and may be administered between 2-5 times.

Opportunity to Create Reimbursement Structures to Support Provider Use of CAR-T

Assignment to one of the three identified likely MS-DRGs would be clinically inappropriate and financially devastating to providers even when treating the most routine, 'uncomplicated' CAR-T patients, as the relative weights of these existing MS-DRGs are woefully inadequate. Therefore, ASBMT urges CMS to create new MS-DRGs for FY 2019 by exercising its authority under Section 1886(d)(5)(I) of the Social Security Act, which allows CMS to "provide by regulation for such other exceptions and adjustments to such payment amounts under [IPPS] as the Secretary deems appropriate." We strongly believe CMS must make a proactive adjustment to the MS-DRG structure for CAR-T payment FY2019 so that it does not hamper beneficiary access to this breakthrough therapy.

Throughout FY2018, providers will be delivering this therapy on a limited basis as the first centers are approved and operationalized by the manufacturers; by FY2019, the volume may reach manufacturer predictions of more 3,000 per year in the beneficiary population. From discussions with individuals in financial leadership positions in the key oncology centers that will be utilizing CAR-T, these cases will receive very high levels of scrutiny throughout the next year as programs assess the impact on their overall finances. The magnitude of financial losses that will be associated with the provision of this therapy at the current level of MS-DRG payment will force many hospitals to examine the capacity and scope of their programs without compromising their solvency as a provider, which is why we are asking for a dual solution between CMMI and CMS' Division of Acute Care in order to create both an immediate and longer-term set of solutions.

While we recognize that CMS is sometimes reluctant to exercise its authority, there is precedent for CMS to make a DRG grouping decision prior to the more standard timeline of waiting two or more fiscal years after a service is introduced. We believe that the case for CAR-T therapy is

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even more compelling than the drug-eluting stents exception over 15 year ago, both from an unmet clinical need and resource-discrepancy perspective. Specifically, in 2003, CMS exercised its authority and created new DRGs 526 and 527 at the time that drug-eluting stents (DES) were introduced into the marketplace to recognize the additional expense of this new technology. ASBMT urges CMS to exercise its authority and mirror this policy initiative by creating two new MS-DRGs for the administration of CAR-T.

Given the resource differences utilized in a case where a patient needs to be treated for cytokine release syndrome or neurotoxicity, creating a MS-DRG for CAR-T and another for CAR-T with complications and comorbidities or major complications and comorbidities CC/MCC would be the most appropriate for both CMS and the provider community.

Inadequacy of Outlier and New Technology Add-On Payments

We hope CMS will work collaboratively between the Division of Acute Care and CMMI to determine a pathway forward. In the separately attached letter to CMMI, we make clear that there is a need for immediate relief due to the inadequacy CMS' existing payment mechanisms, specifically its outlier payment methodology and new technology add-on payments both of which rely, in large part, on hospitals marking-up their invoice cost for the product such that when CMS applies the hospital's cost-to-charge ratio, the resulting calculation results in cost close to the invoice amount.

As CMS would be able to note through an analysis of cost report data, the higher the cost of acquisition for a drug or device, the more reluctant providers are to mark them up. This well-documented phenomenon of 'charge compression' impacts providers real-time in that they will be unlikely to obtain either an appropriate outlier or new technology add-on payment. Furthermore, the charge compression issue impacts providers over time when CMS uses these very claims with poorly aggregated cost data for future rate-setting. We appreciate that CMS has repeatedly instructed providers that they are able to set their charges as they reasonably relate to their costs which also involves providers understanding CMS' uses of the charge data, but in this era of transparency and public scrutiny, providers are not likely to mark-up their $475,000 CAR-T product to over $2 million in charges just to obtain either an outlier payment or new technology add-on payment. Given that neither the outlier or new technology mechanism (if/when it becomes available) is likely to resolve provider reimbursement concerns, we urge CMS to utilize a rate-setting methodology for FY 2019 that will enable providers to be paid appropriately while CMS works on longer term solutions of gathering data on claims and in cost reports that will enable it to avoid issues of charge compression.

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Considerations for Creating Relative Weights for New MS-DRGs

We recognize that under usual rate-setting processes, CMS will not have any CAR-T claims from FY2017 to use for creating the two new CAR-T MS-DRGs we are requesting. As such, CMS will have to utilize a different mechanism for FY2019 rate-setting. Regardless of which option CMS utilizes, it must consider how to provide adequate reimbursement to providers for CAR-T patient care costs which are separate from the high product cost. We believe the following options can be utilized by CMS separately for FY 2019 and/or in collaboration with CMMI given the recommendations we've offered. Additional details of these options are provided in Appendix A.

- **Option 1**: We believe CMS can collect and utilize actual FY2018 claims data for CAR-T cases to model MS-DRG relative weights. While this is a significant departure for CMS in terms of the claims look-back period, it would at least allow the Agency to utilize actual CAR-T claim charges, length of stay and resource use. CMS would need to use manufacturer submitted ASP information to account for CAR-T product costs if it chooses not to require and use separate submission of invoice cost in future rate-setting. We believe CMS must instruct providers to isolate the specific CAR-T drug charge on inpatient claims by detailing the CAR-T product charge in the same manner they do today for blood clotting factors charged for hemophiliac inpatient stays. That is, the CAR-T product should be billed with revenue code 0636 and the product HCPCS code as a distinct and separate line item from all other drug charge on the claim. In this way, CMS is easily able to replace the CAR-T drug charge line with actual ASP information to reflect the CAR-T product portion of the cost that would be made in addition to the newly created MS-DRG which would reflect the patient care portion of the overall inpatient stay.

- **Option 2**: If CMS does not wish to break from its routine rate-setting by using actual CAR-T FY2018 claims, it could use FY2017 claims for cases that are clinically similar and as resource homogenous as possible to CAR-T cases (i.e. similar length of stay and similar costs) and then add a separate payment for the CAR-T drug. This option can rely upon the same ASP CAR-T product reimbursement as Option 1 or provide pass-through drug payment based on actual provider invoice cost. Invoice cost can be obtained by instructing providers to submit their invoices to their Medicare Administrative Contractors in addition to isolating the charge as a unique line item on the claim. Using actual invoices is an interim step until CMS can obtain a unique value code from the National Uniform Billing Committee (NUBC) to report actual CAR-T invoice cost on claims, thereby avoiding the need for ADRs.

- **Option 3**: A third option is for CMS to create relative weights for two new MS-DRGs as described earlier and add to it the average weighted ASP or invoice amounts of the various CAR-T products that are FDA approved as of July 2018. The primary risk with this option is that the ASP and invoice cost of the different CAR-T products can vary widely and that an average will result in either significant overpayment or underpayment of the CAR-T drug. This is problematic for providers and for CMS and we do not recommend using this strategy. We mention it here only because we know that CMS typically relies on the averaging process and we want to advise against the use of this process in this case.

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- **Option 4:** CMS can utilize the mechanism suggested in the ASBMT CMMI letter for fiscal years 2018, 2019, or until it has accurate data based on updated claims and cost reporting data. This option allows the Division of Acute Care to continue using existing MS-DRGs while still allowing providers to be paid separately for the CAR-T product. This also allows the outlier payment mechanism to still be applied to patient care costs reported on hospital claims. We have provided more details in Appendix B about how CMS can achieve a transition back to the regular rate-setting processes after the conclusion of the CMMI payment mechanism.

We recognize our request to the Division of Acute Care for two new dedicated CAR-T MS-DRGs, along with the rate-setting options described above, requires unique action but we believe the Agency has a compelling and justifiable reason to act given CAR-T's status as the first FDA approved gene therapy[10] and Administrator Verma's own comments regarding the Novartis CAR-T product approval: *"[i]nnovation[] . . . [that] reinforce[s] our belief that current healthcare payment systems need to be modernized in order to ensure access to new high-cost therapies, including therapies that have the potential to cure the sickest patients*." We agree that these new therapies have the potential to cure patients and urge CMS to provide fair and adequate reimbursement to providers.

Identification of Different Types of CAR-T Claims Over-Time

Finally, we believe that new ICD-10-CM codes are needed for Cytokine Release Syndrome and, potentially, treatment-related neurotoxicity. These complications would be clinical diagnoses made by the treating specialists upon analysis and review of each patient's physiological and other signs and symptoms. The ASBMT and other stakeholder groups are beginning an evaluation of this need, but we also ask CMS request that the ICD-10 Coordination and Maintenance Committee investigate the need for specific diagnosis codes for these complications. With new diagnosis codes, future claims can easily differentiate between "simple/routine" cases and complicated CAR-T cases. In the absence of specific syndrome codes, the presence of codes for the following symptoms may indicate the present of post-infusion complications: fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias.[11]

Summary and Contacts

ASBMT welcomes the opportunity to discuss identified issues with CMS in hopes that the Agency will choose to utilize its authority under the law to create appropriate reimbursement mechanisms for FY 2019 and over time for this and other new breakthrough therapies. CAR-T is a transformative therapy for the field of oncology and ASBMT is committed to making it

[10] FDA Press Release, August 30, 2017

[11] U.S. Food and Drug Administration, Yescarta Package Insert Accessed October 28, 2017

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available to beneficiaries that may benefit and urge CMS to be a proactive partner in this endeavor. ASBMT peer-elected leaders, member clinicians and policy staff are available as a resource for CMS staff when issues associated with HCT, CAR-T and other cellular therapies are raised internally in the future. Please do not hesitate to reach out whenever we may be of assistance.

Krishna Komanduri, MD
ASBMT President, 2017-2018
Health Policy Staff Contact: Stephanie Farnia, Director, Health Policy; StephanieFarnia@asbmt.org; (847) 725-2316

Appendix A: Claim Modifications to Isolate CAR-T Drug Charge on Inpatient Claims and Report CAR-T Invoice Expense

CMS and hospitals prefer electronic claim transactions where all necessary information is provided directly on claims. To isolate the CAR-T drug charge on inpatient claims, CMS should instruct hospitals to report the specific CAR-T product charge under revenue code 0636 as a separate line item with the product-specific HCPCS code and line item charge on the UB-04 or 837I. This instruction is not new to CMS or hospitals; it is exactly as hospitals are currently instructed by CMS to bill hemophilia blood clotting factors on inpatient claims using revenue code 0636 and the HCPCS code both of which print to the UB.

Furthermore, to obtain provider's actual CAR-T drug invoice cost on claims, we recommend that CMS submit a formal request to the National Uniform Billing Committee (NUBC) for a unique value code for the hospital to report the actual invoice cost of CAR-T products on each applicable claim.

Having this information on inpatient claims will provide CMS all the needed elements directly on the claim to track CAR-T drug costs and isolate it for future rate-setting - that is, the invoice cost of CAR-T with the value code and the amount and the specific line item billed charge for the CAR-T product. Below is an illustration of what the claim would look like.

Example CAR T Inpatient Hospital Claim with Invoice Detail				
				FL04 = 0111
FL12 = Admit Date 10-1-17			FL17=Discharge Date 10-15-17	
	Value Code = xx		373,000.00	
FL 42 Revenue Code	FL 43 Description	FL 44 HCPCS	FL 46 Units	FL 47 Total Charges
0121	Room & Board		14	$ 49,000.00
0250	Pharmacy		100	$ 10,000.00
0270	Supplies		20	$ 1,500.00
0300	Laboratory		520	$ 50,000.00
0636	**Detailed Pharmacy**	**Jxxxx**	**1**	**$ 410,300.00**
0940	Other Tx Services		1	$ 3,500.00
0001	Total Charges			**$ 524,300.00**

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Appendix B: Roadmap to Routine IPPS Rate-setting for CAR-T Cases

We believe there are four components that are required to obtain accurate data and prevent charge compression for high cost drugs and biologicals, like CAR-T including the following:

- Obtaining actual invoice expense and line item billed charge data for CAR-T on claims
- Requesting from NUBC a new dedicated revenue code series for CAR-T
- Creating new dedicated cost center for CAR-T
- Creating a new 20th IPPS cost grouping for CAR-T if CMS continues to use follow its current rate-setting methodology

Further details are provided in Appendix A, but we also believe that the first of these components – obtaining invoice expense and line item billed CAR-T charges on claims – should be implemented immediately under the CMMI authority as part of the demonstration we are requesting. We believe CMS needs to collect invoice cost information for CAR-T products through the duration of its CMMI demonstration in order to have this data available at the earliest possible time rather than ever planning or intending to estimate CAR-T cost from billed charges. Obtaining this data from the outset, would enable CMS to simultaneously provide accurate and fair reimbursement to hospitals providing this important and groundbreaking therapy to patients today under the CMMI authority, while also bypassing/avoiding the entire issue of charge compression under IPPS rate-setting in the future. We believe this methodology will be easy to implement for both providers and CMS as it uses components familiar to both which CMS uses today, in part, for expensive blood clotting factors on inpatient claims. We believe the methodology we have outlined is simple and can easily be utilized to provide fair and appropriate reimbursement to both PPS and PPS-exempt hospitals even with differences in reimbursement mechanics.

It is important to note that even if CMS concurs with all our suggestions and the components needed for future rate-setting, and also acts upon each one post haste, implementation will still take between 2-4 years and gathering data for use in reimbursement processes may take even longer. For example, our best guess on when a new revenue code series would likely be approved for implementation is around July 2019. Furthermore, expense reporting in a newly designated cost center in hospital cost reports is not likely to appear until 2022 or 2023, at the earliest. An interim solution that can be enacted immediately is crucial. It is during this initial post-approval period that we believe CMS will need to obtain invoice cost data, initially with actual invoices being submitted by providers, and as soon as possible after through a value code on claims along with the billed line item charge for each CAR-T drug detailed on inpatient claims so that it can be used to support rate-setting in the near future including – rate-setting that informs future CMMI demonstrations concerning CAR-T.

If CMS acts immediately to collect both invoice cost and drug-specific charge information on claims either through the CMMI demonstration and/or through separate claims processing

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manual instructions to providers, CMS would have usable information for FY2019 rate-setting. CMS would be able to remove the CAR-T drug charge from claims and follow its usual MS-DRG rate-setting method for all remaining charges on the claims. CMS would also be able to calculate the average CAR-T drug costs for the inpatient cases using invoice cost information. Once the weights are established without the CAR-T drug cost, CMS could add back a separately calculated average CAR-T drug cost before finalizing each applicable CAR-T MS-DRG weight. This will avoid charge compression for these products in rate-setting until sufficient data is flowing into the newly designated revenue code and specific associated cost center in hospital cost reports.

We believe that this modified approach to MS-DRG rate-setting is fully defensible given the long-standing history of charge compression combined with the extraordinary expense of the CAR-T drug costs and the fact that these groundbreaking therapies are completely new and not incorporated into any existing hospital cost structures. By CMS taking this "forward looking" approach, it would show the provider and patient communities that the Agency is sensitive not only to cost considerations, but to price transparency and patient access as it relates to these incredible new life-saving therapies.

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