Alliance for Regenerative Medicine

July 10, 2020

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Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: 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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals.

File code: CMS-1735-P

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) 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 2021 Rates Proposed Rule (Proposed Rule).[1] Specifically, we thank CMS for its proposed new MS-DRG 018, Chimeric Antigen Receptor (CAR) T-Cell Immunotherapy and also support CMS' methodologic approach in creating this new MS-DRG. As detailed below, ARM believes this new MS-DRG will dramatically improve Medicare beneficiary access to currently marketed CAR T therapies. In addition, ARM looks forward to working with CMS to further establish greater transparency and payment accuracy within the Inpatient Prospective Payment System (IPPS) for all innovative treatments. ARM believes that these fundamental principles should serve as the foundation for the MS-DRG system that will continue to stimulate and reward innovation in the inpatient setting with further downstream positive impact on other payers such as Medicaid and private insurers.

ARM is an international multi-stakeholder advocacy organization that promotes legislative, regulatory, and reimbursement initiatives necessary to facilitate access to life-giving advances in regenerative medicine worldwide. ARM comprises more than 350 leading life sciences companies, research institutions, investors, and patient groups that represent the regenerative medicine and advanced therapies community. ARM takes the lead on the sector's most pressing and significant issues, fostering research, development, investment, and commercialization of transformational treatments and cures for patients worldwide.

[1] 85 Fed. Reg. 32,460 (May 29, 2020).

The regenerative medicine and advanced therapies sector is the next frontier in the fight against some of humankind's most devastating diseases and disorders. As of year-end 2019, ARM estimates there are 906 regenerative medicine and advanced therapies developers worldwide sponsoring 1,066 clinical trials across dozens of indications, including oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.[2]

As discussed in previous comments, a large subset of these clinical trials focuses on the power of CAR T therapies. These therapies are the first in a wave of new and exciting advanced therapies and technologies that are the next frontier in the fight against some of humankind's most devastating diseases and disorders. ARM is currently tracking the outcomes of the approximately 158 ongoing clinical trials using the CAR T technology in a variety of stages of cancer and cancer types. In addition, ARM tracks hundreds of other clinical trials exploring the power of the immune system, particularly focused on T cells. ARM believes that the new and promising technology of using the patient's own immune system to fight disease provides the possibility that future treatments for many types of cancer at its many stages could be durable and curative. For this and many other reason, ARM agrees with many of CMS' proposals related to creating a new MS-DRG for fiscal year 2021 for a CAR T administration.

I. Executive Summary:

- CMS should finalize its proposal to create new MS-DRG 018.
- CMS should complement the creation of MS-DRG 018 with enhanced billing guidance to hospitals.
- ARM asks CMS to apply the learnings from the CAR T experience to expedite access to the possible forthcoming additional cell and gene therapies.
- ARM urges CMS to evolve its NTAP eligibility policies to further promote access to innovative therapies.
- CMS should recognize certain FDA approval designations for drugs as dispositive for newness and substantial clinical improvement.
- CMS should increase the NTAP payment cap to eighty percent.
- CMS should establish a more frequent NTAP process.
- For purposes of ICD-10 coding, CAR T therapies are therapeutics and not blood or blood products.
- CMS' placement of the CAR T ICD-10-PCS codes in two different tables is confusing and misleading**.**

[2] https://alliancerm.org/publication/2019-annual-report/

II. ARM Urges CMS to Finalize its Proposal to Create MS-DRG 018

The new technology add-on payments (NTAPs) for the current CAR T therapies expire at the end of fiscal year 2020 and ARM is concerned that patient access would be dramatically negatively impacted without a change to current reimbursement policy. ARM is pleased by CMS' proposal to create a new MS-DRG for the expiring NTAPs and for the current CAR T NTAP applicants. Specifically, for fiscal year 2021, CMS proposes "to assign cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 to a proposed new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). If additional procedure codes describing CAR T cell therapies are approved and finalized, we would use our established process to assign these procedure codes to the most appropriate MS–DRG."[3] ARM supports this proposal, is grateful for its establishment, and urges CMS to finalize the creation of new MS-DRG 018.

Further, ARM agrees with CMS that it is necessary to distinguish between clinical trial and non-clinical trial cases in establishing the resources required to provide CAR T-cell therapy outside of a clinical trial. As CMS notes, the average costs for the non clinical trial cases are almost five time higher that the average costs for all cases in MS-DRG 016.[4] Because of this difference, CMS proposes "a differential payment for cases where the CAR T-cell product is provided without cost as part of a clinical trial to ensure that the payment amount for CAR T-cell therapy clinical trial cases appropriately reflects the relative resources required for providing CAR T-cell therapy as part of a clinical trial."[5] ARM appreciates CMS' approach towards establishing a relative weight for the new MS-DRG that is more accurate and reflective of the items and services provided to the Medicare beneficiary. ARM agrees with CMS' proposal "that clinical trial claims that group to proposed new MS–DRG 018 would not be included when calculating the average cost for proposed new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug."[6] To identify the clinical trial claims, CMS proposes to use cases that contain diagnosis code Z00.6 or standardized drug charges of less than $373,000 as the foundation to calculate, in part, the clinical trial adjustment for the CAR T-cell therapy.[7] ARM thanks the Agency for the clarity and transparency in how the Agency will develop the relative weight for the new MS-DRG and appreciates CMS' willingness to develop a more tailored solution to establish payment accuracy and appropriate access.

ARM, however, is concerned that CMS is not using the complete set of charge data in rate setting for the new MS-DRG. Specifically, new revenue code 0891 was established by the National Uniform Billing Committee (NUBC) that ARM believes

[3] 85 Fed. Reg. 32,476.
[4] Id.
[5] 85 Fed. Reg. 32,566.
[6] Id.
[7] Id.

should improve the collection of cost data.[8] ARM encouraged CMS to utilize this new code in its final MS-DRG 018 payment methodology to ensure more appropriate payment for the MS-DRG. Unfortunately, ARM understands that CMS did not include the 0891 charges in its proposed rate setting for MS-DRG 018 as those charges map to the organ acquisition cost center instead of the pharmacy cost center. ARM urges CMS to correct this as soon as practicable. With this information, CMS should have the necessary information to continue to establish an accurately paying MS-DRG for CAR T therapies for FY 2022 and beyond.

Finally, ARM requests that CMS confirm the timely inclusion of CAR T therapies into MS-DRG 018 prior to the creation of corresponding procedure codes, and that there remains an ICD-10-PCS code for administration of an unspecified CAR T therapy. This code for administration of an unspecified CAR T therapy is essential to ensure that CAR T clinical trial cases that do not have product specific codes appropriately map to MS-DRG 018 and ensure that FDA approved CAR T cell therapies for which CMS intends to assign a product specific code can map to MS-DRG 018 utilizing the unspecified code until such time as a product specific ICD-10-PCS code is assigned.

For FY 2021 and beyond, ARM believes that the creation of this MS-DRG establishes a transparent and predicable reimbursement infrastructure for providers that would mitigate or avoid significant financial losses. The new MS-DRG provides a stable approach towards reimbursing new CAR T therapies that will help promote access to these therapies in the inpatient setting. ARM urges CMS to continue to be flexible in establishing reimbursement policies in the IPPS that result in accurate payment, promoting and stimulating innovation, and appropriate and timely access for Medicare beneficiaries. Specifically, ARM believes that other similar exceptions to the standard IPPS formula may be needed in the future to allow hospitals to make other lifesaving therapies available to Medicare beneficiaries.

III. CMS Should Complement the Creation of MS-DRG 018 with Enhanced Billing Guidance to Hospitals to Establish Accurate Reimbursements

As stated above, ARM supports CMS' efforts to create accurate and transparent payment rates for CAR T therapies and therefore urges CMS to further educate hospitals on appropriate billing practices in order to generate more data from which to set accurate and appropriate relative rates and overall payment policy. In analyzing the payments that hospitals will receive under the new MS-DRG, ARM notes that more than half of CAR T cases will result in losses to certain hospitals relative to CAR T acquisition cost and the average non-drug costs of treating CAR T patients. ARM is concerned that this does not afford appropriate and equal access to beneficiaries.

Therefore, should CMS finalize the proposed MS-DRG, ARM urges CMS to issue guidance to hospitals regarding the new MS-DRG and remind hospitals how to

[8] http://www.nubc.org/subscribersonly/PDFs/Cell%20Therapy%20Changes%20August%202018.pdf

accurately and appropriately bill for CAR T therapies. The focus of the guidance should emphasize that CMS' calculations of new technology add-on payments, outlier payments, as well as its calculation of future relative weights, for the new MS-DRG uses cost-to-charge ratios (CCRs) to estimate costs from hospitals' charges. As such, in order for CMS to correctly and accurately estimate the cost of care furnished to Medicare patients within new MS-DRG 018, hospitals must set charges accurately and consistently in line with the relevant CCR.

As noted above and in our previous comments and meetings, there are unique challenges with paying for CAR T therapies under the averaging principles of IPPS. CMS' use of the data in 0891 combined with better billing practices by hospitals should enable accurate weight setting and payments in the future. ARM believes Agency guidance will educate hospitals on the new MS-DRG and more importantly provide for more accurate and uniform billing practices from which to set future reimbursement rates. As such, ARM encourages CMS to undertake this important educational initiative.

Finally, ARM also believes that this request related to billing practices is consistent with and supports CMS' goal of developing a market based approach to payment under the Medicare FFS system. ARM agrees with CMS that the chargemaster rates rarely reflect market costs and that the Agency should move towards a fair-market value payment system and decrease its usage of hospital chargemasters. ARM, however, is concerned that if the Agency should move away from the current system without accurate and current market based pricing information on CAR T therapies, the new system will be flawed because it evolved from inaccurate or otherwise flawed data. ARM encourages CMS to partner with hospitals to collect accurate and appropriate pricing data on CAR Ts and all innovative therapies such that future reimbursement rates will be based on robust and accurate data.

IV. ARM Asks CMS to Apply the Learnings from the CAR T Experience to Expedite Access to the Possible Forthcoming Additional Cell and Gene Therapies

As previously stated, ARM applauds CMS for the steps taken to develop MS-DRG 018 and the associated proposed rate setting methodology. ARM knows that cell therapy is a rapidly evolving landscape with promising new cell therapies such as tumor infiltrating lymphocytes (TIL) and genetically-engineered T-cell receptor (TCR) technologies that are nearing commercial readiness as early as this fiscal year. Therefore, ARM encourages CMS to apply the learnings from the CAR T-cell therapy experience gleaned from the past several rulemaking cycles to expedite reimbursement decisions regarding these novel cell therapies that are anticipated to shortly be on the market. In particular, we look forward to working with the Agency to speed data collection on patterns of clinical utilization and treatment costs related to new-to-market cell therapies so that Agency decisions around initial MS-DRG mapping, the establishment of new MS-DRGs, NTAP grants, and other mechanisms can be made swiftly to facilitate timely patient access and more predictable provider reimbursement.

V. ARM Urges CMS to Evolve its NTAP Eligibility and Payment Polices to Further Promote Access to Innovative Therapies

In 1983 when Congress created the Inpatient Prospective Payment System, regenerative and advanced technologies were closer to science fiction than the clinical reality they are today. As such, Congress likely did not find the need to include a mechanism or methodology that adequately reimburses hospitals for providing these types of new and innovative technologies. However, in efforts to recognize the value of new technologies, Congress, in 2000, required CMS to establish a mechanism to recognize the costs of new medical services and technologies in the inpatient setting for discharges beginning on or after October 1, 2001.[9]

Specifically, Congress instructed CMS to "provide for additional payment…in an amount that adequately reflects the estimated average cost of such service or technology."[10] Further, Congress instructed CMS that this additional payment might be satisfied by means of a new technology group known as an "add-on payment," that is, a payment adjustment or any other similar mechanism for increasing the amount as long as it represents the estimated average cost of such service or technology.[11]

Congress also required that the new technology represent an advance in medical technology that substantially improves the diagnosis or treatment of individuals. As stated above, regenerative medicine and advanced therapies on the market and in the pipeline epitomize Congress' statement on new technologies. Regenerative, cell, gene and immune-therapies have already and will continue to demonstrate substantial clinical improvement by improving health outcomes and hold the promise of reducing overall health care costs. Hundreds of next generation medicine products in clinical trials hold similar promise to treat unmet medical needs, improve patient care, and bend the health care cost curve in ways that current forms of clinical care have not been able to achieve. Many of the diseases targeted by researchers and product developers, such as heart disease, diabetes and musculoskeletal conditions, are chronic conditions that affect millions of American families and are significant cost drivers for Medicare.

In enacting the NTAP program Congress surely did not intend the NTAP program to be a barrier rather than a facilitator of access to new therapies and technologies. Therefore, ARM appreciates CMS' efforts to update some of the NTAP's eligibility criteria and change the current reimbursement rate to be more in line with Congressional intent. ARM believes, however, that without some further improvements to the NTAP program, many of the technologies described above will

[9] SSA §§ 1886(d)(5)(K) and (L).
[10] SSA §1886(d)(K)(ii)(III).
[11] SSA §1886(d)(K)(v).

be out of reach for Medicare beneficiaries, or worse, never be developed due to CMS' insufficient eligibility criteria and payment rate.

A. Immunotherapies' Different Mechanisms of Action and Unique Patient Populations Should Satisfy the Newness Criterion

CAR T and other immunotherapy technologies are at an early stage and have the potential to dramatically improve patient outcomes because they are highly specific and differentiated from each other. They can be personalized for an individual patient and the CAR T technologies are significantly different from one another and from other immunotherapies. Among other things, the CAR design, vector used for genetic transfer, and manufacturing process can all vary substantially between therapies. They are distinct and new cellular products. Therefore, for purposes of satisfying the newness criterion of the NTAP, ARM believes that a manufacturer that demonstrates this should satisfy the newness criterion.

Specifically, CMS established the following criteria for evaluating whether a new technology is substantially similar to an existing technology and therefore meets the newness criterion: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments."[12]

Each CAR T therapy must be tailored to treat a unique combination of clinical indications, safety profiles, and patient populations in order to provide a therapy that is both effective and personalized for each unique patient. It is because of these factors that ARM believes that distinct cellular products with unique manufacturing processes customized for a specific disease and patient, should be considered a different mechanism of action and therefore satisfy the newness criterion. Further, ARM believes that the unique and differentiated patient populations being served by these new technologies meet the NTAP criteria where the cost and substantial clinical improvement criteria are satisfied, notwithstanding the creation of the proposed new MS-DRG 018.

B. ARM believes the Proposed Cost Threshold for MS-DRG 018 is Inaccurate.

CMS proposes to evaluate whether the current CAR T applicants meet the cost criteria for purposes of their NTAP applications using the proposed new MS-DRG 018 threshold amount of $1,237,393.[13] In support of this position, CMS states that "based on information from the FY 2021 Proposed BOR File for Version 38 of the MS–DRGs, the standardized charge per case for MS–DRG 018 is $913,224. The

[12] 85 Fed. Reg. 32,568.
[13] 85 Fed. Reg. 32,644.

average case-weighted threshold amount based on the proposed new MS–DRG 018 is $1,237,393."[14] CMS then states that based on these numbers neither the currently marketed CAR T therapies nor the current NTAP CAR T applicants would satisfy the cost criterion. In response, ARM, along with other stakeholders, conducted their own analysis and believe that these numbers may be based on an in appropriate figure. Specifically, CMS cites $913,244 as the standardized charge per case for DRG 018; however, this figure is the standard deviation charges for those cases. The actual average standardized charge per case, according to the FY 2021 Proposed BOR file for Version 38 of the MS-DRGs is $1,387,946.33, which exceeds the cost threshold for MS-DRG 018. ARM urges CMS to audit its calculations and then reapply the new cost threshold to current NTAP applicants.

C. Similar to Devices, CMS Should Recognize Certain FDA Approval Designations For Drugs As Dispositive for Newness and Substantial Clinical Improvement NTAP Criteria

For FY 2020, CMS implemented a dramatic change in the eligibility criteria for certain devices but not for drugs or biologicals that meet a very similar evidentiary standard. Specifically, starting in fiscal year 2020, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS.[15] Additionally, CMS states that because the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, the medical device would not need to meet the substantial clinical improvement requirement.[16] CMS states that it received 10 applications for new technology add-on payments for FY 2021 under this alternative new technology add-on pathway.[17] ARM views this as a successful policy changes and urges CMS to add drugs and biologicals (drugs) to this recent policy change. Such an approach would signal support for more and better patient access to transformative medical devices and drugs.

For FY 2020, CMS denied adding drugs to this policy stating that "current drug-pricing system provides generous incentives for innovation, but too often fails to deliver important medications at an affordable cost. Making this policy applicable to drugs would further incentive innovation but without decreasing cost, a key priority of this Administration.[18] ARM respectfully disagrees, especially in light of the increase in device applications. ARM believes that the Agency's broad and sweeping statements regarding incentives for innovation for drugs are inconsistent with CMS' other statements regarding the value that innovative therapies bring to Medicare and Medicaid beneficiaries.[19] ARM urges CMS to be consistent in its approach to

[14] Id.
[15] 85 Fed. Reg. 32,676.
[16] 84 Fed. Reg. 19,372.
[17] 85 Fed. Reg. 32,676.
[18] 84 Fed. Reg. 19,672.
[19] 85 Fed Reg. 37,286 (June 19, 2020).

promoting access to all innovative technologies and include drugs and biologicals within the same alternative pathway as applied for devices.

i. Breakthrough Therapy or Regenerative Medicine Advanced Therapy (RMAT) Designation Should be Dispositive for the Newness and Substantial Clinical Improvement NTAP Criteria for Drugs or Biologicals

CMS notes that under the third criterion for a NTAP application, a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries"[20] as a determining factor of substantial clinical improvement. ARM previously stated and continues to believe that this standard was created by Congress and CMS for medical devices as that was the prevailing new technology of the time. This standard, however, should not be applied to regenerative medicine therapies because these criteria are likely outside Congressional intent because it is inconsistent with some of the congressionally created FDA approval rules related to expedited approval programs. Specifically, the FDA defines the congressionally created "breakthrough therapy" and designates a therapy as such if it "may demonstrate substantial improvement over existing therapies." In addition, the Regenerative Medicine Advanced Therapy (RMAT) designation is granted to products that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and if clinical evidence shows that it has the potential to meet an unmet medical need. ARM, therefore, believes that CMS' substantial clinical improvement criteria should not apply to any therapy that has a Breakthrough or RMAT designation from the FDA.

In a previous response to ARM's request, CMS stated that "if the technology has a status designated by the FDA that is similar to the standards and conditions required to demonstrate substantial clinical improvement under the new technology add-on payment criterion, or is designated as a breakthrough therapy, the technology should be able to demonstrate with evidence that it meets the new technology add-on payment substantial clinical improvement criterion.[21] ARM appreciates CMS' stated connection between the FDA designation and its belief that the technology "should be able to demonstrate substantial clinical improvement criterion." ARM, however, questions why CMS continues to raise concerns regarding the substantial clinical improvement criterion for each application that has a Breakthrough or RMAT designation from the FDA and also fails to make this connection for medical devices.

In raising concerns with each NTAP application that has one of the aforementioned FDA designations, it seems to ARM that CMS questions the validity of the FDA designation and the ability of the technology to meet the substantial clinical improvement criterion, which was just satisfied via FDA designation. For example, CMS continues to raise patient mortality data and few published results

[20] 85 Fed. Reg. 32,569.
[21] 83 Fed. Reg. 20,279.

showing survival benefit as concerns for satisfying substantial clinical improvement. Yet, the FDA designated the therapy as RMAT or Breakthrough because it demonstrated substantial clinical improvement based on these same characteristics and then approved it based on the same criteria. The FDA has the authority to revoke the designation should the Agency believe that the therapy no longer meets this criterion such that if the NTAP applicant was approved with a FDA Breakthrough or RMAT designation it should by definition satisfy the substantial clinical improvement criterion.

Similar to the substantial clinical improvement requirement, ARM believes that the current newness criteria are inappropriate for regenerative and advanced therapies. Specifically, CMS established the additional criteria requiring an applicant to show its technology is not "substantially similar" to existing technologies and does not treat the same or similar disease. As noted earlier, products that receive Breakthrough or RMAT designations are by definition determined by the FDA to be an improvement over existing therapies or treat unmet medical needs. If FDA makes this determination, it would be inconsistent for CMS to make a clinical determination that such a product is "substantially similar" to an existing product. Moreover, given the incremental nature of technological advancement, the ability of CMS to determine when a product meets a "newness" standard is not clear.

ii. Clinical Trial Size or Scope on a FDA Approved Orphan Therapy Should Never Disqualify a NTAP Application

In recent NTAP applications, CMS has questioned how clinical improvement can be measured and achieved via the number of or small amount of patients within a clinical trial that generated FDA approval. ARM is concerned that this view sets a dangerous precedent by significantly undervaluing new transformative therapies. Orphan, cell, and gene therapies often target small patient populations as developers are attempting to cure rare diseases or previously untreatable subsets of patients. Therefore, by necessity, the number of and size of clinical trials for these products will be small and frequently can include surrogate measures of efficacy, with long-term post-approval patient follow-up expected. The FDA recognizes this and often only requires single-arm trials with small numbers of patients for these products. Sometimes, even only one trial is required by the FDA. It is often not feasible for product developers to provide data on a large number of patients, especially those working in rare diseases. Given the transformative nature of the products, this should not be a reason for CMS to ever deny an NTAP payment.

In response, CMS states that "it accepts different types of data (for example, peer-reviewed articles, study results, or letters from major associations, among others) that demonstrate and support the substantial clinical improvement associated with the new medical service or technology's use. In addition to clinical data, we will consider any evidence that would support the conclusion of a substantial clinical improvement associated with a new medical service or

technology."[22] ARM appreciates that CMS considers a wide range of data to support substantial clinical improvement, and such additional data have been critical in the development of rare disease medicines for decades. Thus, we believe that an FDA approved trial design, including small, single-arm, and similar data and evidence, should be sufficient for CMS to approve an NTAP application.

VI. CMS Should Increase the NTAP Payment Cap to Eighty Percent

ARM appreciates CMS' new NTAP payment rate which equals the lessor of the costs of the new medical service or technology; or 65 percent of the amount by which the costs of the case exceed the standard DRG payment. The overall NTAP reimbursement formula, however, deflates the overall amount because it focuses on an amount that is the "lesser of" two calculations. Congress instructed CMS to reimburse hospitals an amount that reflects the estimated average cost of the technology. ARM respectfully disagrees that the 65 percent payment rate within the current "lessor of" formula satisfies Congressional intent. ARM remains concerned that while the 65 percent is an improvement over 50 percent this payment amount still does not adequately reimburse hospitals for providing a new technology.

ARM, therefore, urges CMS to cap this rate at 80 percent. Based on ARM's historical data analyses, 65 percent would still require many hospitals to significantly mark-up the cost of the new technology in order to break even; whereas, with an 80 percent cap those hospitals with more conservative marking-up practices can still provide access to beneficiaries. As a general principle, ARM believes that CMS' NTAP payment methodology must be practicable from an implementation point of view at the hospital level while simultaneously allowing for equal beneficiary access in the inpatient setting.

VII. CMS Should Establish a More Frequent NTAP Process

Last year Administrator Verma announced, "a comprehensive strategy to improve patient' access to emerging technologies."[23] Administrator Verma states that the Administration's vision is "to protect and secure Medicare and ensure beneficiaries have access to the latest medical technologies. The advent of novel medical technologies requires CMS to remove barriers to ensure safe and effective treatments are readily accessible to beneficiaries without delaying patient care. In essence, keeping new technologies and treatments moving from bench to bedside—and into the hands of those who need them most."[24]

ARM applauds these statements and looks forward to further working with the Administration to implement the resulting policies. One policy that CMS could change to greatly improve access to novel medical technologies is the frequency of the NTAP. The current process provides for NTAPs only at the beginning of the

[22] Id.
[23] https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-medical-device-manufacturers-association-annual-meeting
[24] Id.

fiscal year. ARM believes that this requirement unnecessarily delays access to innovative and often lifesaving therapies for Medicare beneficiaries. As such, ARM urges CMS to implement a more frequent NTAP approval process consistent with the Administrator's vision and other sites of care such as the hospital outpatient setting. Further, a more frequent NTAP would enhance the quality of data for the Agency to use for rate setting purposes. ARM believes that CMS along with the NCHS could expand the April 1 diagnosis code assignment date to also include NTAPs. In adding a second effective date for NTAPs, CMS would, in theory, have more claims data associated with the new technology to analyze when establishing the next fiscal year's relative weights and provide access to new technologies quicker to Medicare beneficiaries.

VIII. CMS' Placement of the CAR T ICD-10-PCS Codes in Two Different Tables is Confusing and Misleading

In the FY 2021 Tables Addenda for the ICD-10 Procedure Coding System (PCS) CMS established a new table for the procedure codes associated with the FY 2021 NTAP CAR T applications. The table describes the Operation of the procedure codes as "Transfusion: Putting in blood or blood products."[25] Curiously, the current marketed CAR T therapies are listed in a separate table with an Operation descriptor of "Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products."[26] (emphasis added).

ARM is concerned that two of the CAR T therapies are being described as a blood or blood product when each of the products clearly meets the FDA definition of biologic, is regulated by the FDA as such, and clearly meets the Operation description of the existing table because of its therapeutic mechanism of action. ARM appreciates that CAR T therapies are derived from the patient's blood and therefore when administered to the beneficiary could be described as a transfusion of a blood product, but this literal approach of the CAR T administration will likely cause confusion given the CAR T's significant therapeutic benefit as compared to a simple transfusion of a blood or blood product. Each substance behaves very differently in the patient and ARM asks CMS to clarify why it decided to create a new table with this operational description as compared to having the new CAR T therapies in same table as the current CAR Ts.

IX. Conclusion

ARM is confident that meaningful improvements in clinical outcomes and cost reduction can be accomplished through regenerative medicine technologies. ARM believes that the field of regenerative medicine has the potential to heal people and bend the health cost curve toward lower long-term costs and higher quality outcomes. This trend is already evidenced by several approved and marketed first-generation regenerative medicine products that are demonstrating both clinical and

[25] https://www.cms.gov/medicare/icd-10/2021-icd-10-pcs
[26] Id.

cost reduction value. Specifically, by reducing hospital care, the need for physician, clinical and professional services, nursing, and home healthcare, we could substantially reduce overall healthcare expenses.

ARM supports the CMS proposal to create a new MS-DRG for CAR T therapies and many of its methodologies to establish appropriate payment for this MS-DRG. It is critical for CMS to develop and implement policies and programs that support the use of new technologies which is particularly true for regenerative medicine and other advanced therapies that hold the promise of durably treating and potentially even curing disease.

We thank CMS for its many proposals and statements in the Proposed Rule and look forward to working with CMS to establish policies that promote appropriate access to regenerative medicine therapies in both the near term and long. Please free to contact me at rfalb@alliancerm.org with questions.

Sincerely,

Robert J. Falb
Director, U.S. Policy and Advocacy