

November 1, 2019

Mr. Donald Thompson  
Director  
Division of Acute Care  
Mail stop C4-01-26  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

***Via Electronic Delivery to [MSDRGClassificationChange@cms.hhs.gov](mailto:MSDRGClassificationChange@cms.hhs.gov)***

**Re: Request for MS-DRG Reclassification for Certain Cases Involving Use of Chimeric Antigen Receptor T-Cell Therapies**

Mr. Thompson,

On behalf of the Biotechnology Innovation Organization (BIO) and the Alliance for Regenerative Medicine (ARM), we are writing to request reclassification of certain cases using Chimeric Antigen Receptor (CAR) T-cell therapies from their current Medicare Severity-Diagnosis Related Group (MS-DRG) to a new MS-DRG for fiscal year (FY) 2021 that would more appropriately reflect the cost of care for these innovative therapies over time.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapies not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

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. 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 2018, ARM estimates there are 906 regenerative medicine and advanced therapies developers worldwide sponsoring 1,028 clinical trials across dozens of indications, including oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.<sup>1</sup>

We specifically request that CMS establish an MS-DRG for cases using CAR T-cell therapy that is reflective of the true cost of the treatment, and that will be in place to account for loss of new technology add-on payments (NTAP) to hospitals. We further request the agency remove clinical trial cases in establishing a relative weight for this MS-DRG and apply standard hospital adjustments

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<sup>1</sup> <https://alliancerm.org/publication/2018-annual-report/>

to the payments under this MS-DRG. The agency should also consider future opportunities to more closely align payment to cost of treatments to ensure appropriate hospital reimbursement, particularly as additional cost data become available through the more detailed revenue codes that took effect on April 1, 2019.

## I. Background on CAR T-Cell Therapies

CAR T-cell therapies are manufactured from a patient’s own T-cells; those cells are reengineered to attack cancer cells through a highly-specific manufacturing process producing a dose for a single patient. These therapies currently are indicated for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, a subset of incredibly vulnerable and sick cancer patients. Administrator Seema Verma has recognized that these therapies “are an important scientific advancement in [a] promising new area of medicine and provide treatment options for some patients who had nowhere else to turn.”<sup>2</sup> The Centers for Medicare & Medicaid Services (CMS) has implemented coverage policies with the goal of providing “consistent and predictable patient access nationwide” to CAR T-cell therapies.<sup>3</sup> There are currently two CAR T-cell medicines on the market, to treat patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL), KYMRIAH® (tisagenlecleucel) and YESCARTA® (axicabtagene ciloleucel).

Prior to the availability of CAR T-cell therapy, patients with relapsed/refractory DLBCL had median overall survival of 6.3 months and only 7 percent of patients achieved a complete response. Survival for patients who respond to CAR T-cell therapy is measured in years, rather than months.

## II. CMS should establish a new MS-DRG to provide appropriate payment for cases using CAR T-cell therapy.

BIO and ARM recognize that “the primary objective of the [Inpatient Prospective Payment System (IPPS)] is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries.”<sup>4</sup> In addition, CMS has long recognized “the need to keep current with developments in the areas of coverage and medical technology” as one of the objectives of the IPPS.<sup>5</sup> To accomplish these objectives, CMS is required to update the MS-DRGs annually to “reflect changes in treatment patterns, technology, [and] other factors which may change the relative use of hospital resources.”<sup>6</sup>

BIO and ARM strongly believe that the time has come to update the MS-DRGs to reflect expanded coverage and utilization of CAR T-cell therapies outside the context of clinical trials.

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<sup>2</sup> CMS Press Release: Trump Administration Makes CAR T-Cell Cancer Therapy Available to Medicare Beneficiaries Nationwide, Aug. 7, 2019, <https://www.cms.gov/newsroom/press-releases/trump-administration-makes-car-t-cell-cancer-therapy-available-medicare-beneficiaries-nationwide>.

<sup>3</sup> *Id.*

<sup>4</sup> 84 Fed. Reg. 42044, 42653 (Aug. 16, 2019).

<sup>5</sup> 50 Fed. Reg. 35646 (Sept. 3, 1985).

<sup>6</sup> Social Security Act (SSA) § 1881(d)(4)(C)(i).

**A. CMS should create the new MS-DRG in the FY 2021 rulemaking cycle so that it will be in place upon the expiration of NTAP for the currently available CAR T-cell therapies.**

BIO and ARM are greatly concerned that an impending steep cut in reimbursement for cases using these therapies outside clinical trials under the IPPS will harm access to CAR T-cell therapies. KYMRIA<sup>®</sup> and YESCARTA<sup>®</sup> are currently eligible for NTAP, which helps to narrow the gap between reimbursement for their current MS-DRG and the cost of furnishing these therapies to Medicare beneficiaries. Without a new MS-DRG, hospitals will face drastic reductions in reimbursement for these cases if the NTAP for the currently available therapies expires as anticipated on September 30, 2020. The Moran Company calculates that average payments for non-clinical trial CAR T cases in FY 2021 would be \$280,219, including the standard adjustments for wage index, indirect medical education (IME), disproportionate share hospital (DSH), and outlier payments, if they remain in their current MS-DRG. This would be a reduction of 20 percent from \$353,000, the estimated average payment for these cases in FY 2020, including NTAP, outlier payments, and standard adjustments. It is vitally important to address the MS-DRG assignment for non-clinical trial cases using CAR T-cell therapies for FY 2021 so that hospitals can continue to offer, and expand access to, these therapies for Medicare beneficiaries.

Creating a new MS-DRG for non-clinical trial cases also would help to bring stability and predictability to Medicare's payment for these cases and to the IPPS overall. It would reduce hospitals' reliance on outlier payments for these cases, and it would reduce the share of total outlier payments that are attributable to CAR T-cell cases. As a result, it would free up Medicare funds for outlier payments for other types of cases.

**B. CMS should exclude the costs of clinical trial cases from its calculation of the relative weight for the new MS-DRG.**

In establishing a MS-DRG for CAR T cell therapy, we request that CMS base the relative weight for this new MS-DRG using cases where CAR T therapy was provided outside of a clinical trial. The preferred method for identifying these cases would be to include cases where the ICD-10-PCS codes for use of CAR T-cell therapies are present and exclude cases that have codes indicating that the therapy was provided in a clinical trial and/or cases that include only nominal drug charges which also suggest that CAR T cell therapy was provided at no cost to the hospital through a clinical trial. Specifically, cases that would be included in a new MS-DRG would be identified as follows:

**1. Claims must include:**

**ICD-10-PCS procedure codes for use of CAR T-cell therapies:**

XW033C3	Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3
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Or

XW043C3 Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3

And

**2. Claims must not include either:**

**a. Codes for clinical trial services**

**a. ICD-10-CM diagnosis code for services provided in a clinical trial:**

Z00.6 Encounter for examination for normal comparison and control in clinical research program<sup>7</sup>

**b. Condition code 30.<sup>8</sup>**

Or

**b. Only nominal charges for drugs.**

We believe that a unique MS-DRG is needed for these cases because they involve significantly higher costs than other cases in MS-DRG 016, autologous bone marrow transplant with CC/MCC or T-cell immunotherapy. With an average sales price of \$373,000 per dose for the DLBCL indication of the currently approved CAR T-cell therapies, the acquisition cost for the drug alone far exceeds the typical cost of a case assigned to MS-DRG 016. For this reason, the majority of non-clinical trial CAR T-cell cases were “trimmed” as outliers when payment for MS-DRG 016 was set for FY 2020. These differences in cost mean that non-clinical trial cases should be assigned to a new MS-DRG with a different relative weight and standardized payment amount.

In an analysis of the FY 2018 Inpatient MedPAR Final Rule Dataset, The Moran Company calculated the base weight for MS-DRG 016, including CAR T-cell and non-CAR T-cell cases, as 6.867 and the standardized payment amount for the MS-DRG as \$43,016. In contrast, the relative weight for a new non-clinical trial CAR T-cell MS-DRG is calculated to be 37.803, which results in a standardized payment amount of \$236,788. It is important to note that this amount does not reflect the full cost of furnishing CAR T-cell therapies, but it comes closer to the cost of care than the current base MS-DRG payment amount.

	<b>DRG Weight</b>	<b>Number of Discharges</b>	<b>Standardized Payment Amount*</b>
Base Weight for MS-DRG 016	6.867	2,347	\$43,016
Non-Clinical Trial CAR T-Cell MS-DRG	37.803	59	\$236,788

As CMS acknowledged in the IPPS proposed rule for FY 2020, in the case of CAR T-cell therapies, a significant number of cases in Medicare’s claims data using CAR T-cell therapies involve clinical trials, and “the absence of the drug costs” on these claims “could have a significant

<sup>7</sup> This code is required on claims for services provided in a clinical trial. Medicare Claims Processing Manual, ch. 32, § 69.6.

<sup>8</sup> *Id.*

impact on the relative weight” for an MS-DRG for these cases.<sup>9</sup> The Moran Company’s analysis shows that this is exactly the case. As you recommended at an earlier meeting, the Moran Company reviewed the claims data for cases in which a CAR T-cell therapy likely was provided a clinical trial but was not coded as such. We found cases in which the drug charges were far less than the acquisition cost for a CAR T-cell therapy. In these cases, the drug charges likely apply to other drugs provided to the patient, not the CAR T-cell therapy itself. We believe that these cases are in fact clinical trial cases and should be excluded from rate-setting.

The Moran Company’s analysis calculated the relative weight for all CAR T-cell cases (including clinical trial cases) as 16.926, while the relative weight for non-clinical trial CAR T-cell cases was calculated to be 37.803. This 123 percent difference in the relative weight produces a nearly \$131,000 difference in the standardized payment amount.

	<b>DRG Weight</b>	<b>Number of Discharges</b>	<b>Standardized Payment Amount*</b>
Base Weight for MS-DRG 016	6.867	2,347	\$43,016
CAR T-Cell MS-DRG	16.926	166	\$106,020
Non-Clinical Trial CAR T-Cell MS-DRG	37.803	59	\$236,788

**C. CMS should continue to apply the standard adjustments for IME, DSH, and wage index to the new MS-DRG.**

We also recommend that CMS apply the standard adjustments for IME, DSH, and wage index to the new MS-DRG for the non-clinical trial CAR T-cell cases. These adjustments will be essential to ensuring that hospitals receive more appropriate reimbursement for these transformative therapies. The Moran Company calculates that the average hospital payment for a case assigned to the new non-clinical trial CAR T-Cell MS-DRG, including IME, DSH, and wage index adjustments and outlier payments, would be \$437,240.

**III. CMS should consider future opportunities to more closely align payment to the cost of care.**

We note that the claims data for dates of service after April 1, 2019, will include revenue code 0891 (Special Processed Drugs – FDA Approved Cell Therapy - Charges for Modified cell therapy), which will more precisely identify charges for CAR T-cell therapies than the 2018 claims data we reviewed. In the future, CMS could look for this revenue code to identify cases in which there are no charges for the CAR T-cell therapy. When a claim includes charges in this revenue code, we are hopeful that CMS will be able to use the information to set reimbursement rates that do not rely on cost-to-charge ratios to estimate costs. Such a methodology also could remove incentives for hospitals to mark up their charges significantly for these therapies, which could improve beneficiary access to care.

<sup>9</sup> 84 Fed. Reg. 19158, 19181 (May 3, 2019).

We also urge CMS to consider requiring hospitals to report value code 86 with the actual dollar amount of the CAR T-cell therapy product's acquisition cost. CMS can then rely on the data reported in value code 86 to set payment rates for cases using CAR T-cell therapies in the future.

#### **IV. Conclusion**

We urge CMS to create a new MS-DRG for FY 2021 to ensure that hospitals are appropriately reimbursed for the costs of care using CAR T-cell therapies outside of clinical trials. Without assignment to a new MS-DRG upon expiration of the new technology add-on payments for the currently approved CAR T-cell therapies, Medicare's payment for these cases would be far less than the cost of care, placing unsustainable financial burdens on the hospitals that furnish these innovative therapies. A new MS-DRG would help to establish more appropriate reimbursement for these cases, thus protecting access to care for Medicare beneficiaries.

We thank CMS for its consideration of this request and we look forward to meeting with you to discuss any questions you have in detail.

Please contact Crystal Kuntz or Robert Falb at [ckuntz@bio.org](mailto:ckuntz@bio.org) or [rfalb@alliancerm.org](mailto:rfalb@alliancerm.org) with questions about this request.

Sincerely,  
/S/  
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