

July 10, 2020

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Administrator

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735-P
P.O. Box 8013
Baltimore, MD 21244

Submitted Electronically at www.regulations.gov

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 (CMS-1735-P)

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the fiscal year 2021 Hospital Inpatient Prospective Payment System proposed rule published in the Federal Register on May 29, 2020.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

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ASCO supports the establishment of a new MS-DRG for CAR-T; however, we have significant concerns that the reimbursement rate is insufficient to cover the cost of the CAR-T therapy and associated services and will therefore restrict access to this lifesaving therapy.

In response to multiple stakeholder requests, including ASCO, for a new Medicare Severity Diagnosis Related Group (MS-DRG) for procedures involving chimeric antigen receptor T-cell immunotherapies (CAR-T) and given the additional claims data now available on these procedures, CMS proposes to create the MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). If finalized as proposed, any cases reporting the existing CAR-T ICD-10-PCS procedure codes (XW033C3 or XW043C3) would be assigned to this MS-DRG and reimbursed at the national rate of \$239,490 in 2021.¹

As new CAR-T therapies enter the market, we expect that CAR-T and related services will become increasingly available for cancer patients, and we applaud CMS for responding to stakeholder feedback to establish a new MS-DRG for CAR-T. ASCO strongly supports the establishment of a new MS-DRG for CAR-T therapies giving providers the reimbursement certainty they need to offer the therapy; however, we express serious concerns that the reimbursement rate for MS-DRG 018 is insufficient to cover the cost of the therapy and related services, leaving providers in financial loss. In 2020 CMS established a new technology add-on payment (NTAP) for two CAR-T products – Yescarta and Kymriah, which set the national reimbursement rate at \$285,594 in 2020.² Under the 2021 proposal in which the NTAPs for Yescarta and Kymriah are discontinued and a new MS-DRG for CAR-T is established, the base reimbursement amount for CAR-T therapies would be \$133,510 less than the cost of the therapies themselves and \$46,104 less than the total 2020 reimbursement rate. Additionally, we estimate that the average standardized cost of the therapy and related services is \$419,238. Though some cases would be eligible for outlier payments, even the addition of those payments would be inadequate in covering the costs for providers. This leaves providers offering CAR-T and related services under Medicare in a significant deficit.

Table 1. Actual vs. Proposed Reimbursement Rates

Proposed 2021 Reimbursement Rate	Average Cost of CAR-T Drug	Estimated Cost of CAR-T Therapy and Related Services	Provider Responsibility*
\$239,490	\$373,000	\$419,238	\$179,747

*A portion of this amount may be covered with outlier payments, though even with the outlier payment total reimbursement would still be insufficient to cover the full costs incurred by providers

ASCO believes providers should never have to bear the financial burden when payors do not reimburse for the full cost of a therapy; this is especially egregious and unsustainable for high cost therapies as seen in Table 1. Targeted treatments such as CAR-T therapies have enormous potential to cure previously untreatable cancers. If providers are not adequately reimbursed for services rendered, most will be unable to provide this service, which seriously limits patient access. ASCO supports the delivery of CAR-T therapy in all manufacturer-approved, high-quality health care settings where patients can be safely and effectively treated with this very complex and demanding treatment regimen, including all care required for adverse events and follow-up. Medicare should cover the full cost of CAR-T therapy except for any applicable patient or provider cost-sharing that would apply to any other covered drug or therapy under the Medicare program. All patients should be supported by the right therapy at the right time, and this can only happen if providers are reimbursed appropriately and fairly. Providers do not set list prices for drugs or treatments and should not bear the financial burden of any unpaid portion of an innovative cancer care therapy simply because a manufacturer has set a high price.

In order to adequately reimburse providers for CAR-T therapies, ASCO recommends that CMS consider 2 alternative rate setting methodologies: 1) calculate the relative weight for MS-DRG 018 by ensuring that each claim has a standardized charge for the drug cost center that is greater than or equal to \$1,963,158, which is the standardized charge equivalent to the average sales price for CAR-T

² Based on the national, unadjusted rates for hospitals that have submitted quality data and are meaningful EHR users. Excludes IME, DSH, and outlier payment amounts. Assumes a maximum NTAP amount of \$242,500.

therapies; or 2) establish separate add-on payment for CAR-T drugs based on the average sales price, similar to the separate payment that is made for clotting factors.

Option 1: Modify Relative Weight Calculation

ASCO requests that CMS modify the methodology for calculating the relative weight for MS-DRG 018. Specifically, we request that CMS ensure that each claim in MS-DRG 018 has a standardized charge for the drug cost center that is greater than or equal to \$1,963,158, which is the standardized charge equivalent to the average sales price for CAR-T therapies (standardized charge = \$373,000/0.19). For claims with standardized charges below this threshold, ASCO asks CMS to substitute \$1,963,158 for calculated standardized charges. CMS calculates costs from standardized charges using cost-to-charge ratios. Ensuring that claims included in the rate setting process have adequate charges is critical to ensuring that estimated costs and, thus, the calculated relative weight accurately reflect the cost of care. Based on FY2021 standardized charges for drugs in MS-DRG 018, drug charges for CAR-T cases is estimated to be \$1,256,174 on a per case basis. This per case standardized charge equates to a cost of \$238,673. This is significantly below the actual cost of CAR-T, for which the average sales price is \$373,000. By identifying claims with standardized charges below \$1,963,158 and substituting a standardized charge that equates to the average sales price for CAR-T therapies, the costs used in the process for establishing relative weights will more accurately reflect the cost of care.

Table 2. Drug Costs Estimated from Charges

Drug charges, MS-DRG 018	\$145,716,174
Number of cases	116
Estimated standardized charge per case	\$1,256,174
Drug cost-to-charge ratio	0.19
Estimated drug cost per case	\$238,673.04

Given the wide variability in hospitals’ reporting of charges for CAR-T, the fact that the national CCR for the drug cost center may not be appropriate for calculating costs for CAR-T, and the importance of establishing an adequate reimbursement amount for these life-saving therapies, we believe this approach will ensure that FY 2021 reimbursement better reflects actual costs and provides more adequate reimbursement to providers. Implementing this approach is straightforward and consistent with the overall methods used to set MS-DRG relative weights:

- For claims assigned to MS-DRG 018, identify claims with standardized charges below \$1,963,158 for the drug cost center.
- Replace standardized charges on these claims with a standardized charge of \$1,963,158
- Calculate costs and relative weights under the existing methodology

There are many advantages to this approach of using standardized charges derived from the average sales price instead of costs estimated from billed charges:

- This approach would not require a statutory change and could be implemented within the current structure of establishing relative weights. ASCO reviewed the statute and Code of Federal Regulations and believes that the Secretary has the authority to implement this change

without statutory change. The statute and Code of Federal Regulations requires that “CMS assigns, for each DRG, an appropriate weighting factor that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.” This language does not prohibit the methodology change that we are proposing as the replacement standardized charge reflects the relative cost of CAR-T therapies and using this replacement standardized charge would result in a relative weight for MS-DRG 018 that better reflects the relative cost of hospital resources.

- This approach can be implemented immediately with limited administrative burden on the agency. Other alternatives such as establishing a separate cost center for CAR-T and/or other high cost drugs would require a number of years before it could be implemented. For instance, when CMS established a separate cost center for implantable devices, it took a number of years for the cost report to be updated, for the data to be collected and verified, and for the cost center to be used in establishing relative weights.
- This approach would yield a reimbursement amount that better reflects the actual costs involved in treating patients receiving CAR-T and would reduce the financial pressure and losses centers face when administering this treatment.

Additionally, there is precedent for CMS using such an approach. In 2006, proposed Outpatient Prospective Payment System payment amounts for cochlear implant procedures were significantly lower than the actual cost of the device. As part of the 2006 rulemaking period, stakeholders successfully demonstrated that the proposed payment rates for cochlear implant procedures were inadequate to compensate hospitals for the full costs of the device and procedure. Stakeholders conducted an analysis of the median cost of the device based on hospital charges found on claims and compared this median cost to the average sales price for the device illustrating that the device cost calculated from claims was significantly lower than the average sales price. Based on this input, CMS modified its methodology for setting the median costs for device-dependent APCs, including the APC for cochlear implant procedures, for CY2006, which yielded a higher payment amount. Specifically, CMS modified its methodology to set the median costs for device-dependent APCs for CY 2006 at the highest of: the median cost of all single bills; the median cost calculated using only claims that contain pertinent device codes and for which the device cost is greater than \$1; or 90 percent of the payment median that was used to set the CY 2005 payment rates.

Option #2: Add-on Payment

If the above approach is not implemented, we would urge CMS to consider establishing add-on payment for CAR-T. This approach has precedent in that hemophilia clotting factors are reimbursed in this way under the IPPS. Add-on payment for clotting factors was established in statute, so CMS could seek statutory authority from Congress for establishing separate payment for CAR-T.

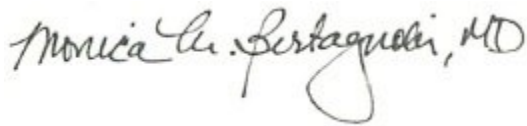
The table below displays estimates of relative weights and payment amounts based on the different approaches.

Table 3. Reimbursement Summary: CMS' Proposal and ASCO Proposals

	CMS Proposal	1) Drug Cost Based on Standardized Charge Equivalent to ASP for CAR-T	2) Add-On Payment for Drug
Relative Weight	37.14	56.09	6.19
Hospital Submitted Quality Data and is a Meaningful EHR User			
Operating amount	\$5,980	\$5,980	\$5,980
Capital amount	\$468	\$468	\$468
National unadjusted payment amount	\$239,490	\$361,665	\$39,902
CAR-T drug cost, if paid separately based on ASP			\$373,000
Total MS-DRG Payment	\$239,490	\$361,665	\$412,902

We appreciate the opportunity to comment on the Hospital Inpatient Prospective Payment System proposed rule. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



Monica Bertagnolli, MD, FACS, FASCO

Chair of the Board

Association for Clinical Oncology