

February 19, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Ms. Verma,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) writes to urge the Centers for Medicare & Medicaid Services (CMS) to consider alternative payment solutions for Chimeric Antigen Receptor T-cell (CAR T) therapy. CAR T is a cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and administered to the patient by infusion to attack certain cancerous cells. Immunotherapies such as CAR T, as well as other new technologies, offer extraordinary potential to save lives, but are also associated with extraordinary costs. For example, CAR T costs \$373,000 for the therapy alone, in addition to patient care costs that may reach hundreds of thousands of dollars.

The AHA is concerned about beneficiary access to CAR T and similar forthcoming technologies given their costliness. As such, we provide recommendations below for near-term, medium-term and long-term actions that promote beneficiary access to these therapies, set appropriate precedents for how they are handled in rate setting and preserve opportunities for additional payment options in the future. In addition to several technical updates we recommend for immediate action, we urge the agency to include the following payment options and technical changes in the fiscal year (FY) 2020 inpatient prospective payment system (PPS) proposed rule for stakeholder consideration and comments:

- Implement a set of coding and technical changes to support more accurate reporting and cost estimation of CAR T services;



- Consider whether an alternative method of determining the cost of the CAR T therapy is needed to ensure the agency captures cost accurately, such as using the therapy's average sales price as a proxy for its cost, using a cost-to-charge ratio of 1.0, or using the CAR T acquisition cost as reported by hospitals (with the new value code available as of April 1, 2019);
- Continue to approve CAR T for new technology add-on payments (NTAPs) and increase the NTAP marginal reimbursement to 100 percent for CAR T, and;
- Consider longer-term solutions for these costly new technologies, such as making payment on a pass-through basis.

In the FY 2019 inpatient PPS final rule, CMS finalized CAR T's Medicare Severity Diagnosis Related Group (MS-DRG) assignment and NTAP approval for two CAR T products. The agency elected not to finalize, however, any additional payment provisions, such as alternative approaches to calculating CAR T product cost (e.g., utilizing a cost-to-charge ratio of 1.0 as discussed in the proposed rule). **Overall, the current system does not ensure appropriate rate-setting or payment for CAR T and similar forthcoming technologies, especially given that NTAPs are temporary. Therefore, we urge CMS to:**

- 1. Implement the following coding and technical changes as soon as possible to support more accurate reporting of outpatient CAR T services and ultimately improve understanding of CAR T services delivered to Medicare beneficiaries.**
 - Change the Healthcare Common Procedure Coding System (HCPCS) Q-code descriptions of the CAR T products to eliminate references to cell collection and processing services, leaving only the product itself represented in the Q-code.
 - Recognize and allow reporting of new Category III Current Procedural Terminology (CPT) codes that describe the cell collection and processing services for CAR T by changing their outpatient PPS status indicators from "B" to "N."
 - Shortly thereafter, reassign the indicators from "N" to "S," which would allow for Medicare reimbursement for these services.

Taking these actions would enable CMS to meet its goal, as stated in the calendar year (CY) 2019 Outpatient PPS Final Rule, "*...to track utilization and cost data from hospitals reporting [CAR T] services, even for codes reported for services in which no separate payment is made.*" We encourage CMS to consider releasing a correction notice that implements the status indicator modification as soon as possible, preferably retroactive to Jan. 1, 2019.

- 2. In the near-term, consider whether an alternative method of determining the cost of the CAR T therapy provided to inpatients is necessary to ensure the agency captures cost accurately before data are available,** such as using the therapy's average sales price as a proxy for its cost, or using a cost-to-charge ratio of 1.0 (as mentioned in the proposed rule). Starting April 1, 2019, the agency also

could use the actual acquisition cost as reported by hospitals on claims by requiring use of the National Uniform Billing Committee (NUBC) value code 86 (as mentioned below). Doing so may be necessary because the standard method of calculating CAR T costs could vastly underestimate the cost of this therapy. Specifically, if a hospital's overall cost-to-charge ratio (CCR) is 0.25, when applied to the list price for one of the CAR T products, it results in a calculated cost of \$93,250, whereas the actual cost is \$373,000. If a hospital with an overall CCR of 0.25 were to adjust the charge of the CAR T product, it would need to set a charge of almost \$1.5 million in order to generate an accurate cost calculation. As such, we agree with CMS that some hospitals may not set charges significantly different from the cost of CAR T. Therefore, using an alternative method that more accurately identifies the cost may be necessary to make accurate reimbursement – it would allow the full cost of the therapy to be appropriately considered, free from charge compression.

- 3. Also in the near term, implement the following technical changes, which will support a more accurate cost estimate of CAR T in the future.** Specifically, NUBC has recommended a series of new revenue codes associated with cell/gene treatments. AHA recommends that CMS utilize these codes in addition to the procedure codes not only for processing claims but also for refinements to the Medicare Cost Report.
- Require hospitals to submit their invoice cost using value code 86, beginning April 1, 2019.
 - Instruct hospitals to utilize the new revenue codes approved by NUBC, beginning April 1, 2019:
 - Revenue code 0891 (from new category 089x) – indicating the cell or gene therapy product charge, and
 - Revenue code category 087x – indicating charges for procedures performed by staff for the collection, processing and infusion/injection of genetically modified cells.
 - Create a new line for CAR T in the Medicare cost report, similar to CMS' development of line 0077 for stem cell transplant. This dedicated cost center would allow CMS to isolate the costs of CAR T in the cost report in order to calculate an accurate, CAR T-specific CCR that would apply in future MS-DRG weight-setting, as well as outlier payment and NTAP calculations.
 - Implement a Medicare Code Editor edit requiring either the presence of a clinical trial diagnosis code Z00.6 and condition code 30 or a non-zero dollar value (including a token charge) in new NUBC revenue code 0891 when either of the ICD-10-PCS CAR T administration codes (XW033C3 or XW043C3) is on the claim. Since these claims exclude the product cost, CMS should also consider excluding them from NTAPs (but they would continue to qualify for outlier) and excluding these claims when CMS is evaluating new MS-DRGs for CAR T and other cell and gene therapies.

4. Increase the NTAP marginal reimbursement to 100 percent for CAR T.

Cases involving certain new technologies may be eligible for NTAPs if the technology is considered to be new, inadequately paid otherwise and a substantial clinical improvement over previously available technologies. By regulation, the NTAP is equal to 50 percent of the marginal cost of the technology in excess of the MS-DRG payment — including adjustments for indirect medical education (IME) and disproportionate share hospital (DSH) — with a maximum payment of 50 percent of the cost of the technology. Per statute, NTAPs may be approved for new technologies for up to three years.

Unlike most new technologies, the amount of losses a hospital faces under a CAR T NTAP rate of 50 percent are in the hundreds of thousands of dollars. With a presumed cost of the CAR T product at \$373,000 and DRG payment of approximately \$37,000, the costs of the case exceed the MS-DRG payment by \$336,000; therefore Medicare would make an NTAP payment of one half of this,¹ approximately \$168,000. When combined with the MS-DRG payment, the total payment for this case would be \$205,000 – a shortfall of \$168,000 for the hospital before considering patient care costs. In addition, in light of their costliness, CAR T cases most likely qualify for outlier payments. However, with a 100 percent marginal NTAP rate, more funding would come through the NTAP mechanism and less through the budget-neutral outlier pool, lessening the redistribution from core to specialized services.

5. Provide relief for PPS-exempt cancer hospitals. Certain cancer hospitals are exempt from the inpatient PPS; Medicare instead pays them based on their reasonable costs, subject to a ceiling. Cancer hospital inpatient reimbursement is capped by a per-discharge amount based on decade-old data that does not account for new treatment modalities. These hospitals received no relief in the FY 2019 Inpatient PPS Final Rule and are not eligible for NTAPs or outlier payments. The agency has authority to provide relief for cancer hospitals. One mechanism could be the use of a CCR of 1.0. For cancer hospitals, this mechanism would best be implemented through standard cost-reporting processes. Specifically, we recommend the following steps:

- Cancer hospitals report the acquisition costs of CAR T-cell on their cost report. This could be done either on subscribed line 73.01 on Worksheet A or on a new, separate, standard line item on the cost report.
- Cancer hospitals force the value of line 73.01 (or the new separate line created in step one above) on Worksheet B-1 to zero. Doing so would prevent overhead from accruing and increasing the calculated cost of the CAR T product.
- Medicare Administrative Contractors (MACs) allow the additional costs from line 73.01 (or the new separate line created in step one above) to be added to the

¹ Medicare pays the lesser of 50 percent of the cost in excess of the MS-DRG amount or 50 percent of the cost of the new technology.

final settlement Worksheet E-3, Part 1. This would prevent any inadvertent recoupment of the interim CAR T-cell therapy payments based on claims. Line 16 or 17 on Worksheet E-3 Part 1 could be used to accomplish this.

Through this mechanism, CAR T-cell therapy drug costs would be added to the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) settlement line at the time of desk audit and treated as allowable costs. CMS also could adjust each institution's target amount upward for a cost reporting period by the product of its number of CAR T-cell treatments furnished in that period multiplied by the institution's actual, direct cost incurred (no overhead) for each treatment. Either of these approaches would provide fair and timely reimbursement to the PPS-exempt cancer hospitals.

- 6. Consider long-term solutions for these costly new technologies, such as making payment on a pass-through basis.** This is especially necessary given that both new and existing therapies are expected to be approved for additional indications. The current payment systems – of any payer, not just Medicare – were not built to sustain access to therapies with costs of these magnitudes. As technology continues to advance, therapies such as these will become more and more prevalent, and it is critical that a precedent is set that ensures beneficiary access to care. This requires not only appropriate payment, but also provider certainty in terms of coverage determinations, as one post-care-provision denial would be devastating to both providers and beneficiaries.

In addition, AHA urges CMS to continue exploring the creation of a new MS-DRG for gene therapies like CAR T in the future; its eventual implementation could potentially provide much more accurate reimbursement for these treatments. Specifically, the weight of this new MS-DRG would directly reflect the extremely intensive resources involved in the provision of CAR T and similar therapies since they would not be averaged together with much less resource-intensive treatments.

We appreciate your consideration of these recommendations and look forward to continuing to work with CMS on these issues of great importance to hospitals and Medicare beneficiaries. If you have any questions, please feel free to contact me or Erika Rogan, senior associate director, policy, at (202) 626-2963 or erogan@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy