March 06, 2020

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

Re: Request for Guidance Regarding Charges for Chimeric Antigen Receptor (CAR) T-Cell Therapies

Dear Mr. Thompson:

On behalf of the Biotechnology Innovation Organization (BIO) and the Alliance for Regenerative Medicine (ARM), we are writing to request that the Centers for Medicare & Medicaid Services (CMS) issue guidance to hospitals regarding appropriate charges for Chimeric Antigen Receptor (CAR) T-cell therapies in light of Medicare's current rate setting methodologies. This guidance, which could be issued in the form of an MLN Matters article, would help to reassure hospitals about the charging practices needed in the current year to produce accurate estimates of cost and set appropriate payment amounts under CMS's reimbursement methodologies in place for FY2020. We continue to support the development of payment methodologies, including our most pressing request that CMS establish a new MS-DRG for CAR T-cell therapy for FY2021, that would more accurately reflect hospitals' costs of care.

Medicare's calculations of new technology add-on payments and outlier payments, as well as its calculation of future relative weights, under the Inpatient Prospective Payment System (IPPS) use cost-to-charge ratios (CCRs) to estimate costs from hospitals' charges. In order for CMS to correctly estimate the cost of care furnished to Medicare patients, hospitals must set charges for CAR T-cell therapies in line with the relevant CCR. In practice, however, hospitals do not apply uniform mark-ups to the items and services they furnish. They often apply lower mark-ups to higher cost therapies compared to other therapies subject to the same CCR. CMS has long recognized that this practice, known as "charge compression," can lead to inaccurate estimates of cost and skewed calculations of relative weights.[1] These inaccuracies result in inappropriately low payment for higher cost new technologies, such as CAR T-cell therapies, which can harm access to care.

[1] *See, e.g.,* 73 Fed. Reg. 48434, 48451-53 (Aug. 19, 2008) ("RTI found that a number of factors contribute to charge compression and affect the accuracy of the relative weights. [. . .] We acknowledge, as RTI as found, that charge compression occurs in several cost centers that exist on the Medicare cost report.").

We understand that some hospitals are reluctant to set charges for CAR T-cell therapies that are in line with the CCR, and as a result, applying the standard CCR to their charges will underestimate the cost of CAR T therapies. We ask CMS to address this concern by providing short, clear guidance to hospitals that they "can appropriately adjust their charges" for these therapies "so that calculated costs properly reflect their actual costs." This is precisely the response CMS provided when asked for clear guidance on charges for radiopharmaceuticals.[2]

We ask CMS to issue an MLN Matters article for FY 2020, similar to the article recently issued on new technology add-on payments for innovative antibiotics,[3] that includes a statement such as the following, which mirrors the guidance CMS provided on radiopharmaceuticals:

> We acknowledge hospitals' concerns about the use of the CCRs resulting in cost compression. We believe that hospitals have the ability to set charges for CAR T-cell therapies properly so that charges converted to costs can appropriately account fully for their acquisition and overhead costs. Hospitals can appropriately adjust their charges for these therapies so that the calculated costs properly reflect their actual costs.[4]

We believe this guidance would address important concerns that affect hospitals' willingness to provide CAR T-cell therapies to their patients right now. For future years, we continue to recommend that CMS consider ways to mitigate markup issues and more closely align payment to the cost of care.

Thank you for your consideration of this request. Please contact Crystal Kuntz or Robert Falb at ckuntz@bio.org or rfalb@alliancerm.org with any questions.

Sincerely,

/S/
Crystal Kuntz
Vice President, Healthcare Policy & Research
Biotechnology Innovation Organization

/S/
Robert Falb
Director, U.S. Policy and Advocacy
Alliance for Regenerative Medicine

[2] 70 Fed. Reg. 68515, 68654 (Nov. 10, 2005).
[3] Increasing Access to Innovative Antibiotics for Hospital Inpatients Using New Technology Add-On Payments: Frequently Asked Questions, SE20004, Jan. 21, 2020, https://www.cms.gov/files/document/se20004.pdf.
[4] 70 Fed. Reg. 68515, 68654 (Nov. 10, 2005).