Research

A Path Forward for CAR-T Therapy Reimbursement Under the IPPS

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Executive Summary

- Chimeric Antigen Receptor (CAR) T-cell therapy is a relatively new and powerful cancer treatment that greatly benefits patients, including the Medicare population.
- Under the Inpatient Prospective Payment System (IPPS), each treatment yields significant monetary losses for hospitals, making access to CAR-T more difficult for patients.
- Since CAR-T's New Technology Add-On Payment is also expiring, one solution is to create a new, specific cell line therapy Diagnosis-Related Group that increases hospital reimbursement per case, making it more broadly accessible to patients.

Introduction

Chimeric Antigen Receptor T-cell therapy—referred to as CAR-T in this piece—is a form of immunotherapy that utilizes the patient's own immune system to attack cancer and is considered the "fifth pillar" of cancer therapies.[1] By modifying the patient's T-cells with an engineered, synthetic receptor specific to their cancer, the patient's body becomes capable of recognizing and attacking the tumor while leaving normal cells alone.

One of the first applications of CAR-T in adults is Yescarta, which treats relapsed large B-cell lymphoma. Fairly quickly, however, CAR-T has been investigated—and is under development—for the treatment of multiple myeloma, a cancer disproportionately affecting Medicare patients.[2]

CAR-T promises to save lives while limiting the side effects of more conventional cancer therapies, but the inadequate reimbursement of such a personalized treatment approach is proving to be prohibitive, particularly for Medicare patients. Because hospitals do not receive full reimbursement for the cost of CAR-T, they are reluctant to offer or prioritize it. To solve this problem, Medicare can create a new billing category specifically for CAR-T, although this category will require some exceptions due to the overwhelming proportion of the total cost of treatment being the drug product itself.

Current Status of CAR-T Medicare Reimbursement

Acute care hospitals are reimbursed for Medicare patients through the Inpatient Prospective Payment System (IPPS), which bundles payments for hundreds of clusters of conditions according Medical Severity Diagnosis-

Related Groups (MS-DRG, or DRG for short). IPPS typically works in the following way. A Medicare patient is admitted to the hospital and placed into a DRG based on their principal diagnosis. From there, a series of adjustments are performed based on their geographic area, complexity of the case, and hospital-specific characteristics. For more information on determining payment rates under the IPPS, please see this American Action Forum primer.

The process of CAR-T reimbursement is typical of any case under the IPPS but requires a fair bit of patchwork to reach the current but insufficient rates, yielding some degree of payment uncertainty for hospitals. If a patient is to receive CAR-T therapy, they are grouped not into their own DRG but rather designated under *DRG 016: Autologous Bone Marrow Transplant with Complications or Major Complications (CC/MCC) or T-Cell Immunotherapy* because it is the closest DRG that the Centers for Medicare and Medicaid Services (CMS) has to CAR-T in terms of clinical characteristics and the medical resources used for treatment.[3] From there, a new technology add-on payment (NTAP) for the CAR-T therapy is made along with an additional outlier case payment due to its high cost.

Issues with Current Reimbursement Scheme

The problems with the current reimbursement system are three-fold. First, current levels of reimbursement are inadequate for hospitals, leading to monetary losses for each treatment. Second, the ability to extend the NTAP for CAR-T treatments is expiring in September, 2020 and—because it has been three years since CAR-T received approval by the Food and Drug Administration (FDA)—CMS does not have the legal authority to provide a one-year temporary extension.[4]

Hospital Reimbursement

The list price CAR-T therapy runs at about $373,000.[5] In fiscal year 2020, the average CAR-T case payment under the IPPS is about $353,000 which includes the NTAP, outlier payments, and all hospital-specific adjustments. Once the operating and capital payments are estimated and factored in, the average total DRG payment come short of covering the full price of treatment and administration by about $50,000 as seen in Table 1. This results in serious losses for the hospital for each CAR-T treatment and impedes the ability of patients to receive this life-changing therapy.

Table 1: 2020 CAR-T Payment Disparities Per Case

Actual Cost of CAR-T Administration*	Base DRG 16 Payment	Maximum NTAP Payment	Outlier Payment and Other Adjustments*	Total DRG Payment*	Disparity from Actual Cost*
$403,000	$43,000	$242,450	$67,550	$353,000	-$50,000

**These numbers are averages and may fluctuate based on hospital and clinical-specific characteristics. More information on payment rate calculations can be found here.*

In addition to the current losses of about $50,000 per case, in fiscal year 2021—should a new DRG not be created and CAR-T remain in DRG 16—the expiration of the NTAP will result in the average payment under the IPPS dropping to around $280,000. As a result, hospitals will face additional losses of about $73,000.

NTAP Extension

NTAPs are designed to be a temporary bridge between new technologies and more stable payment options through a new DRG. As stated above, however, the NTAP for CAR-T is expiring and incapable of being extended due to it passing the three-year FDA approval period. Typically, the process for transitioning these NTAPs to stand alone DRGs is straightforward, but in this case transition is complicated by the fact that most cases under DRG 16 are standard autologous bone marrow transplants, not CAR-T cases. Since DRG payment rates are set based on data from prior years, the small proportion of CAR-T cases paid under DRG 16 do not shift the payment up significantly from year-to-year, leading to an inability of DRG 16 payment rates to "catch up" to the reimbursement levels needed for CAR-T. All of these issues taken together logically demonstrate the need for a permanent split of CAR-T reimbursement from DRG 16.

Solution

The straightforward solution to this issue of CAR-T therapy reimbursement is to create a new, specific cell line therapy DRG, separating CAR-T from DRG 16 entirely. This new designation would significantly boost hospital reimbursement without requiring an NTAP, ensuring hospitals can more favorably consider CAR-T in the treatment line, all to the substantial benefit of the patient. Establishing a new DRG would require CMS to consider, however, that the principal cost of treatment is the therapy itself and neither operational nor capital-related costs—factors that affect the reimbursement, as noted below. CMS would have to accommodate for that fact in the final rule for 2021.

CMS Authority

CMS has the authority to establish new MS-DRG codes for the following fiscal year, tying them to specific codes in the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) and/or the ICD-10, Clinical Modification (ICD-10-CM).[6]

Tying the New DRG to the ICD-10

In the case of CAR-T therapy, a new DRG should be established using the ICD-10-PCS codes *XW033C3: Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 3* and *XW043C3: Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 3*. Using these two codes would cover all billable procedures involving CAR-T therapy, thus divorcing it entirely from *DRG 016: Autologous Bone Marrow Transplant with Complications or Major Complications (CC/MCC) or T-Cell Immunotherapy*. DRG 016 would also need to be modified to prevent overlap between the two.

Other Considerations

To reiterate, the primary cost of CAR-T therapy is not its administration within a hospital system, but the cost of the treatment itself. The DRG payment determination for CAR-T must take this high cost into account by

establishing a sufficient adjusted base payment rate. As a result, IPPS mechanisms such as the wage index will have limited utility for tailoring the final payment to the specific patient or hospital. Due to this fact, the wage index should either not be applied to the new DRG, or the DRG should be established such that the wage index minimally impacts reimbursement.

With the cost of CAR-T in mind, the other major consideration is the impact of including clinical trials on the perceived cost per treatment. Since the cost of drugs are not factored into a case treated through a clinical trial, including clinical trials involving CAR-T in payment rate determination skews the true cost. Payments for CAR-T must be set solely for non-clinical trial cases in order to accurately capture the price. While this would be a deviation from the normal payment rate-setting process under the IPPS, the high cost of CAR-T necessitates CMS make an exception in order to ensure reimbursement is adequate and thus patients more readily receive it.

Conclusion

CAR- T therapy is among the most innovative and astounding medical advancements in the past couple of decades. Cancer patients both young and old stand to have their lives saved after a single treatment course, circumventing some if not much of the suffering imposed by multiple rounds of chemotherapy and radiation therapy. Seeing as the technology is becoming more established and applicable by the year, it is appropriate to guarantee adequate provider reimbursement for this therapy under the IPPS through the establishment of its own MS-DRG.

[1] https://www.cancer.gov/news-events/cancer-currents-blog/2017/car-t-cell-multiple-myeloma

[2] https://www.cancer.gov/news-events/cancer-currents-blog/2017/car-t-cell-multiple-myeloma

[3] https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0044.html

[4] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.27.6.1632

[5] https://www.ashclinicalnews.org/online-exclusives/cms-proposes-coverage-car-t-cell-therapies/

[6] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software