

**Q CASE STUDY**

Ensuring appropriate payment for transformative therapies to secure patient access to CAR Ts

THE CLIENT

A coalition of CAR T manufacturers and their trade association joined together to advocate for appropriate reimbursement of Chimeric Antigen Receptor T-cell (CAR T) therapies. They requested that policy options be developed by non-partisan experts that would best benefit the industry making the drugs, Medicare and Medicaid programs paying for the treatments, and the Medicare beneficiaries receiving these transformative therapies.

BACKGROUND

CAR T therapies first entered the market in late 2018. These transformative treatments for certain types of cancer involve modifying a patient's own cells to fight the cancer—producing a long term, potentially curative response. Initially, CAR T therapy was administered to patients in the inpatient hospital, where Medicare payments are bundled so that the hospital gets a single payment for the entire hospital stay. The cost of the CAR T therapy greatly exceeded the payment rate the hospital would receive, leading to concerns that hospitals would be reluctant to provide CAR T.

APPROACH

The emergence of CAR Ts represented a new reimbursement problem that required very careful consideration because these new treatments were just the beginning of a series of new, expensive, but essentially curative treatments. Solving the CAR T problem would have implications for the future, as other new therapies entered the market. Finding the right solution involved a real rethinking of the inpatient payment system. The client had to recognize how CAR T cases were similar to past precedents — and how some key differences about these cases required fundamental changes to how these cases are paid. Solving CAR T access and reimbursement issues required different types of expertise and approaches. The client needed a very deep understanding of the intricacies of the payment system, as well as a broad view of the policy landscape to find the right balanced response.

The HMA Medicare team had two vital sets of skills that were necessary for the work. First, we have an in-house library of Medicare claims and the data analysis skills needed to use the data to answer policy questions. This includes our model of the Inpatient Prospective Payment System (IPPS) rate setting and payment methodologies, so we could model the policies as they stood, as well as alternative policies to explore which options maximized the goals of the coalition members while minimizing negative outcomes. Second, we have a deep understanding of the policy issues at play, the history of the policy space, and the understanding of the interplay between many policy factors.



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HMA worked with the coalition to monitor Medicare claims to get an accurate picture of the hospitals performing CAR T therapy and the payments they were receiving. We also explored how potential changes to the IPPS could provide better reimbursement for CAR T cases. Using our expert-level understanding of the intricacies of the payment methodology, we modeled many different policies to pinpoint the option that would balance the need for more appropriate payments with the needs of the rest of the system—understanding that there was a pipeline of additional CAR T therapies poised to enter the market in the coming years. This process also involved communicating with the policymakers at the Centers for Medicare and Medicaid Services (CMS) to ensure that the policies being advanced were politically viable and sustainable.

RESULTS

The work culminated in the creation of a new payment category for CAR T cases, with changes to the typical rate setting and payment methodology to account for both clinical trial and non-clinical trial cases. In addition, the work of the coalition prompted CMS to increase payments in the New Technology Add-on Payment program for all products, not just CAR T therapies. As a result, patient access to CAR T therapies has been maintained, and CMS has a framework to work from as new cell and gene therapies become available to Medicare patients. We have seen the volume of CAR T claims increase more than 9-fold over the 6 years the therapies have been available.

At the urging of the CAR T coalition and other stakeholders, CMS created a new MS-DRG (payment category) for CAR T claims, bumping the base payment rate for the cases from ~\$40,000 to ~\$240,000. In addition, NTAP payments increased from a maximum of 50% of the cost of the product to 65% of the cost of the product—this applies for all NTAP eligible claims, not just CAR Ts.

This work involved years of analysis and collaboration that is continuing. While inpatient reimbursement has improved, concerns are arising now around access to CAR T in the community setting.



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