ASSOCIATION OF CANCER CARE CENTERS

IMMUNO-ONCOLOGY INSTITUTE

The Economics of CAR T-Cell Therapy

Bringing CAR T-Cell Therapy to Community Oncology

Chimeric antigen receptor (CAR) T-cell therapy is a rapidly growing area of oncology that has been transforming cancer care since its initial approval for acute lymphoblastic leukemia in 2017. Since then, there have been 5 additional US Food and Drug Administration (FDA) approvals of CAR T-cell therapy for the treatment of various hematologic malignancies, including lymphomas, B-cell leukemia, and multiple myeloma. These treatments have led to markedly improved response rates and long-term survival, significantly surpassing other available anti-cancer therapies.[1] The unprecedented outcomes come with a plethora of challenges, including the management of severe adverse effects as well as logistical and financial challenges that pose major access barriers to the equitable use of CAR T-cell therapy.[1,2]

Most notably, the costs associated with CAR T-cell therapy greatly precludes its widespread use from the perspective of the patient and the provider. While oncology has always been linked to expensive therapies, CAR T-cell therapy products are some of the most expensive treatments to date. The acquisition cost of CAR T-cell products ranges from $373,000 to $475,000, which does not include all the associated costs, such as inpatient admission stays, extra procedures, treatment of cytokine release syndrome (CRS), and similar expenses.[3] Moreover, it has been estimated that the total costs associated with CAR T-cell therapies can exceed $1 million per patient.[2] These exorbitant sums would be easier to absorb if insurance reimbursement practices—particularly Medicare and Medicaid—were adequate to cover much of the total cost, but unfortunately, reimbursement for CAR T-cell therapy has been largely insufficient.

As part of its educational initiative, **Bringing CAR T-Cell Therapies to Community Oncology**, the Association of Community Care Centers (ACCC) examines the economics of CAR T-cell therapy from the perspective of patients and providers in practice.

The Path to Reimbursement

When CAR T-cell products were first approved, they were reimbursed through the New Technology Add-on Payment (NTAP) program, which only covered up to 50% of the product cost; this meant that hospitals were at risk for substantial losses of up to $300,000 for every use of a CAR T-cell product.[2] In 2020, the Centers for Medicare & Medicaid Services (CMS) increased NTAP payments to 65% coverage, but this reimbursement was still largely inadequate for most hospitals. Finally in 2021, CMS created a diagnosis-related group (DRG) specific to CAR T-cell products (MS-DRG 018), which was initially set at $239,929 for the unadjusted base payment.[2] Although the establishment of a separate DRG for CAR T-cell

therapies was an important step, many clinicians expressed concerns that this base payment rate was considerably less substantial than the 2020 reimbursement rate.

For FY 2023, the unadjusted payment rate is approximately $299,460.[4] In addition to the DRG base payment, hospitals may be able to receive supplementary payments in the form of outlier, fixed-loss, or add-on payments. Moreover, 2 CAR T-cell products—brexucabtagene autoleucel (Tecartus) and idecabtagene vicleucel (Abecma)—still have NTAP status and may receive additional NTAP payments, and ciltacabtagene autoleucel (Carvykti) was recently designated to share NTAP status with Abecma.[5] While these extra payments may help to supplement the reimbursement received from CMS for CAR T-cell therapy administration, the total reimbursement is still well below the average cost of delivering CAR T-cell therapy and managing its complications.

Furthermore, as many payers have not yet recognized CAR T-cell therapy as standard of care, therapy is oftentimes treated as experimental which prompts payers to follow Medicare guidelines for reimbursement. This has further impeded the development of a much-needed robust billing model.

The Perils of Lengthy Prior Authorization

Quantity aside, another critical issue in this space has been the protracted time frame of prior authorization reviews and reimbursement payments. Depending on the patient's insurance, the prior authorization review process can take anywhere from several days to several weeks. As the patient eligibility process for CAR T-cell therapy is complex and includes a thorough financial assessment of patients, institutions typically wait for coverage confirmation before proceeding with further clinical evaluation of the patient. Unfortunately, due to delays in insurance approval, patient care suffer.

According to Brittney Baer, BSN, RN, and patient care nurse coordinator for the Immune Effector Cell Program at Vanderbilt-Ingram Cancer Center, "Multiple patients have died waiting for their CAR T-cell therapy to be approved by insurance." Moreover, even with approved prior authorization, institutions continue to wait many months to receive reimbursement payments. These delays in insurance reviews and payments need to be addressed as more CAR T-cell products come to market in the coming years.

Another obstacle specific to patients on Medicaid is the need to be treated in the state in which they hold Medicaid coverage. For patients who live in areas where CAR T-cell-authorized institutions are sparse or absent, Medicaid presents a major barrier to a patient's ability to travel out of state to receive CAR T-cell therapy. Additionally, there is no reimbursement from government insurance programs to cover the costs of travel and lodging for CAR T-cell therapy, which represents a significant portion of indirect costs associated with therapy. Patients and providers must often rely on pharmaceutical companies and charity organizations for potential assistance to alleviate financial toxicity. Such assistance, however, is often fraught with complication due to federal laws prohibiting manufacturers from paying patients to use their medications.[2]

Potential Solutions

The current climate of reimbursement is unsustainable for hospitals to be able to continue to provide CAR T-cell treatments to the growing number of patients who could benefit from this treatment. Experts in the field have suggested various methods to address some of these reimbursement issues. The American Society of Clinical Oncology (ASCO) has proposed that CMS should either "ensure each claim has a standardized charge equivalent to the average sales price for the therapy" or implement a separate add-on payment based on the average sales price of the CAR T-cell product.[2]

Another successful method to improving reimbursement has been the administration of CAR T-cell therapy in the outpatient setting. Outpatient administration is considerably more profitable than inpatient, and in cases where the patient is not admitted to the hospital within 72 hours after the infusion, the entire episode can be billed as an outpatient service. For this reason, cancer programs, such as Vanderbilt-Ingram Cancer Center in Nashville, Tennessee, and and City of Hope in Duarte, California, have transitioned their CAR T-cell therapy programs to a fully outpatient service. This not only enhances reimbursement but increases the overall accessibility to these therapies for patients.[6] Outpatient administration, however, is not a simple solution, as institutions must have many resources and protocols in place as well as rigorously trained staff to handle the intensive virtual and ambulatory monitoring required for these highly complex treatments.

Advocacy efforts continue to play a vital role in improving the financial landscape for CAR T-cell treatment. Professional organizations, such as the American Society of Hematology (ASH) and the American Society for Transplantation and Cellular Therapy (ASTCT), have been urging CMS for years to provide more adequate coverage of CAR T-cell therapies. Public commentary on new policies allows organizations to provide input on potential changes before they are implemented. For instance, the FY 2023 Inpatient Prospective Payment System proposed rule reflected certain requests from ASTCT regarding "a different set and kind of MS-DRGs that would reward providers for controlling patient care costs, without consideration of product costs outside of their control; and evaluation and creation of multiple MS-DRGs for cell and gene therapy cases: one to cover patient care costs, the other to cover product costs across therapeutic product categories."[7]

Ultimately, the biggest catalyst for change will likely be time and more CAR T-cell therapy approvals to drive insurance programs to fully acclimate to these therapies and understand their value. As data accumulates and matures, reimbursement coverage should expand to meet the demand for these treatments. If reimbursement coverage does not catch up, patients stand to suffer the most.

"Jugna Shah, MPH, CHRI, president of Nimitt Consulting and a strong advocate for CAR T-cell therapy reimbursement shares this: We are standing on the cusp of radical medical and scientific innovation, having potentially curative, life-saving therapies reaching the market, yet knowing that all of the patients who need them simply will not be able to get them because our existing government payment models are not designed to handle the cost. We're rapidly approaching a tipping point and unfortunately it will be patients who suffer by not getting these new therapies. The industry needs to have an honest conversation about how payers, providers, patients, and the pioneers of these therapies are going to make our payment systems work better so that patient access is not compromised."[8]

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