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Timely CAR-T Access: Perspectives From Experts

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INTRODUCTION

Chimeric antigen receptor-T cell (CAR-T) therapy is an FDA-approved treatment that uses genetically modified autologous T cells to target specific types of cells.¹ CAR-T therapy has substantial direct and indirect costs; it can take weeks for insurance approval and manufacturing to complete before patients can receive their infusion.^{1,2}

On July 26, 2024, the *American Journal of Managed Care*® (AJMC®) convened expert stakeholders for a virtual roundtable entitled “Timely CAR-T Access: Perspectives From Experts.” This roundtable was moderated by **Zahra Mahmoudjafari, PharmD, MBA, BCOP, FHOPA**, clinical pharmacy manager for the division of hematologic malignancies and cellular therapeutics at the University of Kansas Health System. Roundtable participants included **Peter Ferreira-Gandolfo, MBA; Misha Hawkins, MSN, RN, OCN**; and **Elise Babcock, RN**. This conversation highlighted the barriers for timely access to CAR-T cell therapy including lengthy approval processes, payer education gaps, and administrative burdens on healthcare providers and treatment centers. These burdens encompass complex documentation requirements, multiple authorization steps, and coordination challenges across various stakeholders. Finally, the group worked to identify solutions to streamline these processes and improve overall access to CAR-T therapy.

THE CRITICAL ROLE OF COLLABORATION

Treatment delays are an important factor that may reduce the clinical benefits of CAR-T therapy.¹ Furthermore, the treatment may be less successful in patients with worsening disease progression before administration of CAR-T.¹ Shortening wait time for CAR-T therapy may reduce mortality, especially in patients who have aggressive disease.¹

In addition to delays, the high manufacturing costs of CAR-T therapies hinder access to treatment.³ Necessary steps in the therapeutic process include leukapheresis, lymphodepleting therapy, and treatment of adverse effects, which further increase costs.³ Moreover, outcomes such as the overall response rate and progression-free survival have been used to limit coverage of CAR-T therapy by payers, further limiting access to treatment.⁴

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Due to these challenges, treatment centers, professional societies, manufacturers, and policymakers must coordinate efforts to improve access to care and ensure that all stakeholders, and particularly physicians, are educated on timely referrals and the importance of prompt treatment.⁵ As a result of the complexity of CAR-T therapy, insurance authorization can often take more than a week; this creates difficulties for patients who have active or rapidly progressing disease. Therefore, it is important to provide education to payers to reduce the time to treatment approval.⁵ More rapid treatment can also be achieved by developing standardized methods for large-scale CAR-T therapy production to reduce manufacturing times.⁵ Finally, barriers to access can be reduced by implementing financial assistance programs to fund care partners, psychosocial support, and respite care including lodging and transportation, as patients are required to remain near the administering facility for at least 4 weeks following CAR-T therapy.⁵ Alternative payment models that are not based on outcomes may also help to bridge payment gaps and increase patient access to treatment.^{4,5}

EDUCATING DECISION MAKERS AND PAYERS ON CAR-T THERAPY

Cancers of patients eligible for CAR-T therapy are typically refractory to other treatments.⁶ Depending on the type and dosage of other treatments received and whether these agents may adversely affect T cells, patients expected to receive leukapheresis may need to have a washout period of days to months before the procedure.⁶ After assessment and review of these patients, insurance and authorization are reviewed.^{5,6} Next, autologous collection of white blood cells is obtained via leukapheresis.⁵ Autologous collection aims for minimum CD3+ cell and absolute lymphocyte counts before sending cells to the manufacturer.⁶ The patient's cells are then sent to the manufacturer for reprogramming, which involves incorporating viral DNA coding for CARs into the T cells to transform them into CAR-T cells.⁷

While awaiting CAR-T cells, the patient undergoes a short round of bridging chemotherapy to impair disease progression prior to lymphodepleting chemotherapy.⁶ When

CAR-T cells have been manufactured, patients undergo lymphodepleting therapy with chemotherapeutic agents to prepare their immune systems for CAR-T cells.⁶ Lymphodepletion enables optimization for CAR-T cell count expansion after infusion, improves clinical efficacy, and prevents immune responses against CAR-T cells.^{6,8} After lymphodepletion, the modified T cells are reinfused into the patient, who then receives care during recovery and toxicity management.^{5,6}

Clinical Profile of CAR-T Therapy and Ways That It Differs From Stem Cell Transplants for a Payer

Health insurance plans previously considered CAR-T therapy to be a process similar to hematopoietic stem cell transplant (HSCT).⁵ However, these processes have evolved to be quite different; helping payers to understand these nuances is instrumental to improving conversations regarding necessary testing and imaging. In autologous HSCT (aHSCT), a patient is treated with high-dose chemotherapy to overcome resistant cancer cells.⁹ Patients are then infused with their own hematopoietic stem cells to increase the blood supply and mitigate the adverse effects of the chemotherapy.⁹ This treatment is typically effective in patients who have previously responded to other therapies including chemotherapy and who have achieved near or complete remission.⁹ In CAR-T therapy, on the other hand, T cells are collected from the patient's immune system, genetically modified to recognize cancer cells, and then injected back into the patient, where they exert their action by binding to and killing tumor cells.⁹

Testing and imaging requirements vary for these treatments. Further, payer requirements also vary, which leads to confusion, delays, and unnecessary costs to obtain the appropriate items needed prior to CAR-T therapy approval. Roundtable panelists expressed that there are difficulties with payer understanding of diagnostics for CAR-T therapy and the financial implications of unnecessary testing. Elise Babcock, RN, noted that insurance companies tend to consider CAR-T therapy similarly to aHSCT without having a good understanding of the differences between the 2 treatments. This misunderstanding can lead to requests for unnecessary tests and increased costs



for both patients and health care systems. Misha Hawkins, MSN, RN, OCN, explained that payers often look for specific transplant-related diagnostics that can slow down the process of approval—the degree of urgency is very different, in that prior authorization (PA) of HSCT may take months, but CAR-T therapy may be urgent or need to be planned in weeks. These diagnostics, she elaborated, may include pulmonary function tests, echocardiograms, mammograms, psychosocial evaluations, dental examinations, colonoscopies, and other testing after patients may have already returned home and may require more time for coordination and completion. The process of scheduling these diagnostics and receiving approval can be arduous; if not completed efficiently, patients are at risk of losing their scheduled slot for CAR-T therapy.

Peter Ferreira-Gandolfo, MBA, described another burden to the PA process at his institution. One insurer changed the process by dividing the approval into multiple components that were similar to those used for aHSCT—approval is needed for each component (eg, medication, inpatient stay, and lymphodepleting chemotherapy). Thus, the process of that payer is slowed down compared to those of payers who authorize all aspects of CAR-T therapy at once. Not only are different tests required, but the timing of these tests may vary between payers. For instance, Ferreira-Gandolfo noted that 1 payer may require a PET scan from the past year, whereas other payers would accept PET results from the previous 6 months. Thus, the process becomes complicated if specifics for each health plan are not known.

Educating Payers

Mahmoudjafari asked panelists which current payer policies align and do not align with appropriate patient selection criteria. The overarching sentiment was that more education is necessary for payers to have a better understanding of CAR-T therapy itself as the cell therapy field continues to expand and evolve. At his institution, Ferreira-Gandolfo stated that education is often necessary for staff of smaller payer plans, as they are generally less familiar with CAR-T therapy. Additionally, the approval process for these plans can be more tedious; they often require peer-to-peer reviews. Babcock and Hawkins echoed Ferreira-Gandolfo's observations, explaining that additional education is often necessary when working with new or different reviewers who are less familiar with CAR-T therapy or who have backgrounds in different specialties. This situation frequently leads to increased administrative burden and delays in the approval process. Furthermore, Babcock said, her institution has asked CAR-T cell manufacturers whether their market access teams could contact and give additional education to payers who may have more difficulty approving CAR-T cell therapy. Hawkins also reported a need for payer education about the use of tocilizumab to manage toxicities of CAR-T therapy; she has run into difficulties when patients receive treatment in the outpatient setting, and she had to create workarounds to bypass these denials.

UNDERSTANDING THE PATIENT JOURNEY AND PROCESS BARRIERS

Barriers to improving efficiency arise from documentation and PA of therapies. Participants mentioned specific times when different PAs

were the issue—and it was not always the same type of PA that caused the delay. Participants agreed that delays in approvals lead to increased direct medical costs and indirect costs for payers, the health care system, and patients. Mahmoudjafari mentioned that with delays in therapy, patients often need to start bridging therapy, which can require hospital admission, increase toxicities, and lengthen the hospital stay. Babcock echoed this sentiment, noting that while patients wait for CAR-T therapy, their myeloma or lymphoma may rapidly progress and lead to additional rounds of bridging therapy and possible hospitalization that may not have otherwise occurred. In some cases, she stated, delaying therapy may ultimately lead to repeating steps of the process including diagnostics (eg, an echocardiogram) to ensure it is still safe for the patient to receive CAR-T therapy. Participants added that these delays lead to more patient visits, time away from work, and stress on the family and patients.

The innovation is moving far faster than their ability to keep up just given the number of indications that have evolved since the approvals and then just the sheer volume.

—Zahra Mahmoudjafari, PharmD, MBA, BCOP, FHOPA

Timelines for approval by payers do not always line up with the timeline for the clinical team. Babcock noted that insurance companies may not prioritize PA, and approval may not come until 48 hours before the set date of leukapheresis. Not knowing the status of insurance coverage until so close to the procedure can make reliable planning for treatment difficult, and Babcock noted that this tight of a timeline is not realistic. A further delay to the process may occur when a patient's CAR-T therapy is deemed to be out of specification. In this case, Babcock noted, it may take an additional 7 to 10 days for the research/manufacturing process; this leads to a prolonged bridging therapy that may then delay patient cell count recovery and push back safe receipt of CAR-T therapy. Mahmoudjafari highlighted that the immense amount of paperwork that needs to be submitted can be burdensome. In addition, delays occur when documentation requirements are not met, as when information from provider notes is missing despite best efforts to have a template for the necessary data.

Leveraging real-world evidence on CAR-T effectiveness and improved toxicity management could help demonstrate value to payers and support more timely approvals. Participants emphasized the need for payers to base approval decisions on real-world data rather than on clinical trial data alone and on the differences between treatments;

thus, payers must understand these treatments in greater detail. Babcock's institution has had ongoing discussions with reviewers or in peer-to-peer evaluations to address the differences between the clinical trial data and eligibility criteria, as much clinical trial data do not pertain exactly to real-world practices and patients. Hawkins has observed this. She stated that health insurance companies may know about prior patient participation in clinical trials with the same target; although these 2 strategies are different and providers have specific indications for the requested therapy, payers may view them as the same treatment and deny claims.

I agree that our payer colleagues are in need of further education as the cell therapy space expands.

—Zahra Mahmoudjafari, PharmD, MBA, BCOP, FHOPA

Reimbursement Challenges

Due to the high cost of CAR-T therapy, reimbursement continues to be a challenge with restrictions to CAR-T therapy further impeding patient access.⁴ The panelists identified billing code difficulties and aspects of outcomes-based agreements as challenges to the reimbursement process. Managing billing codes for CAR-T therapy presents challenges because of the complexity and variation compared with those used for other treatments. Billing for CAR-T therapy involves multiple parts of the process including leukapheresis, bridging therapy, lymphodepleting therapy, and toxicity management, and different coding may be needed for each step. Hawkins described that a review team came to her institution to assess billing practices and ensure accuracy as they focused on the differences between CAR-T therapy and transplant procedures. This included conducting case studies and comparing billing practices across different payers for CAR-T patients versus individuals receiving other treatments. The goal was to identify discrepancies and improve the billing process. She explained the need for a more streamlined approach. A uniform set of billing codes specifically for CAR-T therapy would greatly simplify the billing process, reduce errors, and ensure appropriate reimbursement. By standardizing the codes, the billing process could become more efficient, minimize the potential for mistakes, and ensure that all appropriate codes are applied at the right time.

Participants agreed that outcomes-based agreements also pose challenges due to the strict definitions of disease progression and timelines; they suggested that these agreements have less stringent requirements for disease progression. Throughout the discussion, other challenges to reimbursement were brought up. Babcock noted difficulties for a patient whose insurance company rejected reimbursement for the

entire CAR-T process after it had occurred; that payer reviewed claims at the end of the process. Hawkins described that her institution is an exempt diagnosis related group that has a different reimbursement model; they are still working to fully elucidate what comprehensive reimbursement looks like with different cell therapies.

Implications for Patient Care and Support

Members of a care team have many considerations when planning a program offering CAR-T therapy.¹⁰ All participants agreed that transparency in the patient's CAR-T journey is lacking in terms of related co-payments, patient-reported outcomes, and patients' overall treatment costs. In initial discussions with patients, Babcock recommends that patients check with their insurance companies to better understand out-of-pocket costs, which may be influenced by the time of year and, in some cases, the amount of a deductible met. Patient support programs exist, but the specific criteria of these programs may not pertain to many patients. Babcock mentioned that it would be helpful if there was no income requirement for patients to receive benefits from support programs. She added that although some companies are more flexible on income requirements, newer companies tend to not be. Support programs for underinsured or uninsured patients are generally available through manufacturers of CAR-T therapy, but not all companies provide this assistance. Social work teams can help find additional resources; challenges remain, however, particularly with lodging patients who need treatment urgently. Assistance programs follow similar guidelines, but details vary. Hawkins also noted that a major issue is that many patient who are older than 65 years and on Medicare do not qualify for available assistance, because they have federal insurance.

Many companies manufacturing CAR-T therapy offer patient assistance programs to help cover costs such as co-pays, deductibles, local lodging, and travel.¹⁰ However, explained Hawkins, the lodging and travel benefits may be limited if patients do not receive care at the nearest authorized treatment center and instead prefer treatment elsewhere. She also mentioned that patients may end up paying out of pocket to receive treatment at a center not technically the closest to them if they received care at that location prior to CAR-T therapy. Ferreira-Gandolfo suggested that patients may want to go to a specific facility closer to family for their care to have that support system. The ability to accommodate caregivers and their availability to assist patients with keeping appointments, taking medications, monitoring for toxicities, and providing emotional support is a large concern that is complicated when patients are unable to receive care at a facility near their caregivers without incurring extra expenses.⁵

ALIGNMENT STRATEGIES

Opportunities to Streamline Documentation and PAs

An authorizing body that can perform administrative review and approval may help streamline processes involved in obtaining insurance approvals before proceeding with treatment.¹¹ This group can include billing and finance representatives and clinical administrators to ensure that all aspects of treatment are approved before initiating

purchasing.¹¹ Babcock highlighted that over the past year, her program began holding monthly meetings with a multidisciplinary team that involved clinical, finance, business, and PA colleagues. The team reviews information on patients and proper billing codes. Babcock explained that this multidisciplinary approach has helped to reduce stress for the finance and clinical teams, improve communication, and prevent denials from becoming irreversible. Mahmoudjafari and Hawkins echoed that their organizations are also trending towards forming multidisciplinary committees to help streamline their processes.

Participants in the roundtable discussion spent considerable time discussing the need for shorter manufacturing turnaround times and standardization of processes across different manufacturers. The purchase order (PO) process was identified as an area for improvement, and participants had suggestions for its streamlining across different manufacturers. Babcock reported, “On our end, POs have been a major obstacle, mostly because of the turnaround times.” Some institutions have a chain of command for approvals due to the high cost of CAR-T medications and different financial thresholds at which therapies may require additional approval for medications. The timing of PO submission is also a difficulty, reported Babcock. The process they particularly struggle with is having to wait to enter a PO number into the patient’s dashboard. This waiting period, however, may result in patients losing their slot for treatment if it is not entered into the dashboard prior to the scheduled therapy or per manufacturers’ timelines. Further, having a number of individuals involved in the chain of command when approving a PO can delay the process by several days. As an example of success, Hawkins stated, “Our PO process is so streamlined that we can obtain a PO in an hour or 2.” What has helped with their success is having a dedicated team of 3 individuals who exclusively process POs for CAR-T therapy. With this standardized process, they can complete a PO for late apheresis treatment in 2 hours as they also reduce costs.

There was a strong call for greater standardization of processes across different manufacturers especially as new companies enter the market. The panelists expressed that an important part of standardizing the manufacturing process would be a shorter time from referral to time of infusion with shorter manufacturing timelines. Babcock discussed a patient who was unable to receive CAR-T therapy due to disease progression as the therapy was being manufactured, which took 6 weeks. She emphasized the need to carefully consider processing and manufacturing times especially in the case of myeloma. She then noted that the manufacturing time for different products may be a big factor in choosing a product. The group agreed that an ideal timeline from referral to infusion would be 2 to 4 weeks including manufacturing time and, ideally, closer to 2 weeks before disease progresses too much and patients require additional bridging therapies. The panelists also would like to see streamlined manufacturing time for out-of-specification products. Ferreira-Gandolfo suggested that there be more standardization between manufacturers and courier services or creation of a standard courier service; this would help mitigate difficulties that his institution and pharmaceutical companies have had with past couriers. Additionally, he recommended optimization of communication among manufacturers and distributors to the treatment team through a single inbox/email address, especially as more gene therapies are developed. Hawkins

also added that standardization among portal requirements in terms of data needed to input and process would be helpful; it would decrease some of the burden of constantly learning new processes and needing different information.

MEASURING SUCCESS

Mahmoudjafari asked participants what metrics would define success in terms of authorization efficiency and improving access to the CAR-T process. According to the group, the length of time for approval of CAR-T therapy would be 1 metric from the date of submission to the date they receive the letter of approval from health plans. Hawkins noted that creating a strategic database that includes details of those payers who may be less likely to give approval as well as time to approval and required documentation from payers can provide metrics to measure progress in improving access. Mahmoudjafari added that the previously agreed upon 2- to 4-week timeline from referral to infusion would be a metric to define success and ensure that CAR-T therapy is readily available; this would be much better than having to wait for limited options for therapy slots. Improvements in the chain of communication, especially with insurance plans, were also noted as a metric important for measuring authorization efficiency. Patient-reported metrics such as support received during treatment, financial burden, and outcomes, according to the participants, are also lacking.

I think [that it is important that] the manufacturers band together and lobby for what the patients need. You know, the bottom line is the patient.

—Misha Hawkins, MSN, RN, OCN

CONCLUSION

In summary, shared priorities across stakeholders are needed to improve patient access to CAR-T therapy with an emphasis on educating payers on timely approvals, manufacturing time, invoicing of procedures, and clarification of information needed by payers. Specifically, there is a need to reduce the time between when cells are collected from the patient and when they are infused. Additionally, there is room for standardization and streamlining processes on the payer end in terms of consistent invoicing of procedures and the information needed by insurers to proceed with therapy, especially as more therapies come to market.

Payer education emerged as a critical factor in improving access to CAR-T therapy. Panelists emphasized the need for ongoing education,

particularly for smaller payer plans and new reviewers who may be less familiar with CAR-T therapy. As the field of cell therapy continues to expand and evolve, increased payer understanding is essential for streamlining approval processes, reducing delays, and ensuring timely access to treatment for eligible patients.

Aligned solutions across manufacturers to ensure timely access to care with patients' best interests at the forefront of decisions was suggested by Hawkins. Considering what patients need and improving affordable access to care is needed. Mahmoudjafari echoed that solutions to improve turnaround and cell processing services are needed. Ferreira-Gandolfo noted that access to standard courier service among the manufacturers is an additional solution to improve timely access to CAR-T therapy.

As innovation with CAR-T therapy continues, a commitment to ongoing collaboration for improved patient outcomes is needed. Solutions to increase access to CAR-T therapy, noted Mahmoudjafari, include improvement in turnaround times from referral to infusion, increase in scalability of therapies, expansion of CAR-T therapy to community locations, and education to facilitate outpatient administration of these treatments. ●

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