Delivering on CAR T-cell Therapy's Promise:

Policy Solutions for the Next Era of Cancer Care

Foreword

Delivering on CAR T-cell Therapy's Promise: Policy Solutions for the Next Era of Cancer Care, was made possible through funding provided by Kite, a Gilead company. As a leader in CAR T-cell therapy, Kite is committed to breaking down access barriers in the healthcare system and broadening access to this transformative treatment. Kite believes every eligible patient should have the opportunity to receive CAR T-cell therapy—and the potential for a cure.

Executive Summary

CAR T-cell therapy offers a groundbreaking treatment option for patients with relapsed or refractory hematologic malignancies, yet access remains severely limited – only 2 in 10 eligible patients receive this potential curative therapy.[1] Barriers include geographic concentration of treatment centers, complex referral and authorization processes, high financial and logistical burdens for patients and caregivers, and systemic challenges in care coordination and reimbursement. While clinical and policy progress has improved safety and delivery models, urgent action is needed to close the access gap. As CAR T indications expand beyond blood cancers into solid tumors, autoimmune, and inflammatory diseases, the number of eligible patients who would benefit from CAR T will increase in parallel. Growth in this space underscores the need to modernize health systems and reform financing and delivery models to ensure access is not constrained by geography, infrastructure, or outdated payment structures. This paper outlines strategies to promote timely access, reduce patient and caregiver strain, expand treatment capacity beyond academic medical centers, and modernize health system infrastructure and financing to ensure sustainable delivery of advanced therapies.

Background

CAR T (Chimeric Antigen Receptor T-cell) therapy is an advanced form of immunotherapy in which a patient's own T lymphocytes are genetically engineered to

[1] CAR T Vision Steering Committee. *Vision for CAR T-cell therapy: Executive Summary — Expanding Availability of CAR T-cell Therapy*. London: CAR T Vision; 2025.

recognize and kill cancer cells. In practice, T cells are harvested from a patient, modified in a laboratory to express receptors (CARs) that bind to antigens on cancer cells, multiplied in number, then infused back into the patient.[2] The treatment is often given as a one-time infusion (after preparative work), rather than chronic therapy, with proven potential for sustained remission in patients with *relapsed or refractory* (R/R) hematologic malignancies and even cure in some settings. Since the first Food and Drug Administration (FDA) approval in 2017, CAR T has become one of the most important innovations in oncology, providing durable –and in some cases, curative--treatment options for patients, particularly those that have resistant cancers. Despite the clinical potential access to CAR T remains severely constrained; in the United States (US) only about two out of every ten eligible patients receive CAR T therapy.[3] The key accessibility challenges include logistical, geographic, financial, infrastructural, and regulatory barriers.

An Abbreviated History of CAR T

Since 2017, CAR T therapies have provided FDA approved lifesaving and life extending treatments for patients across the United States. Kymriah (FDA approval August 2017) and Yescarta (FDA approval October 2017) marked the beginning of CAR T's transition from experimental therapy to clinical practice. Prior to their approval, treatment options were limited, especially for those patients relapsing from cancers and those with diseases resistant to chemoimmunotherapy.[4] For example, patients once expected to live only six months or relapse within a year, would now have durable treatment options extending their life expectancy for years.[5]

While CAR T represented a potentially life-saving treatment for patients with few remaining options, its use was also associated with complex and sometimes life-

[2] American Cancer Society. *CAR T-cell Therapy and Its Side Effects.* American Cancer Society. Accessed October 28, 2025

[3] CAR T Vision. *Executive Summary – Expanding Availability of CAR T Cell Therapy.* Published 2025. Accessed October 28, 2025.

[4] *Neelapu, SS, Locke, FL, Bartle NL, et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. New England Journal of Medicine. Vol. 377, No. 26. 2017;377:2531-2544. DOI 10.1056/NEJMoa170744*

[5] Sattva S. Neelapu et al. Five-Year Follow-Up Analysis of ZUMA-5: Axicabtagene Ciloleucel in Relapsed/Refractory Indolent Non-Hodgkin Lymphoma. J Clin Oncol 0, JCO-25-00668 DOI:10.1200/JCO-25-00668

threatening side effects, including cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS). These complications could develop rapidly and required specialty expertise to recognize and treat at a time when clinical experience was still emerging given the novel nature of the therapy. The risk of severe toxicities prompted the FDA to require CAR T products to be distributed under a Risk Evaluation and Mitigation Strategy (REMS) program.[6] This program established stringent conditions for use including formal site certification, mandatory physician and staff training, and patients to stay at or near infusion centers for up to 30 days. While The REMS framework safeguarded patients during the early-stage adoption of these novel therapies, it also limited CAR T delivery to a limited number of highly specialized academic and transplant centers. In practice, this meant only institutions with the infrastructure, staffing, and regulatory capacity to comply with REMS requirements could offer CAR T treatment, creating significant geographic barriers for patients seeking access to a CAR T treatment center.

During early implementation of CAR T treatment delivery, patients were typically hospitalized for both the infusion and the critical post-treatment observation period as medical teams require immediate access to anti-cytokine therapies (i.e., tocilizumab and corticosteroids). In response to evolving clinical experience, professional societies including the American Society for Transplantation and Cellular Therapy (ASTCT) developed consensus grading systems for CRS and ICANS that gradually standardized management practices. These safeguards ensured regulatory compliance, protected patients safety and built the foundation for easing or the eventual removal of REMS requirements for certain products.[7]

In this early period, CAR T administration was limited to large academic medical centers and specialized transplant programs which were able to meet the standards of these medical innovations. The Foundation for the Accreditation of Cellular Therapy

[6] U.S. Food and Drug Administration. *Risk Evaluation and Mitigation Strategies (REMS).* Food & Drug Administration. Accessed October 28, 2025.
[7] Alliance for Regenerative Medicine. *Alliance for Regenerative Medicine Applauds FDA's Elimination of REMS Requirements and Labeling Changes for Autologous CAR-T Cell Therapies.* Washington, DC: Alliance for Regenerative Medicine; June 27, 2025. Accessed October 28, 2025.

(FACT) was pivotal in establishing a set of standards to promote high-quality and safe delivery of CAR T.[8] FACT, which first focused on hematopoietic stem cell transplantation, later expanded to include immune effector cell (IEC) therapies. FACT developed voluntary accreditation standards for staffing, facilities, laboratory practices, data collection, and adverse event management to ensure CAR T was introduced in a tightly controlled clinical environment. However, it also reinforced concentration of therapy within a limited number of highly specialized large academic and transplant centers that were often located in dense urban areas. Over time, FACT standards have been gradually adapted to permit expansion into select non-transplant academic sites. A FACT working group recently published fit-for-purpose framework, Standards for Immune Effector Cells in the Community Clinical Setting[9], to expand FACT's accreditation standards into community-based centers, with the goal of bringing CAR T closer to where patients live.

When CAR T therapy fist came to market, manufacturing timelines posed significant challenges as early processes were complex and centralized, often requiring several weeks from cell collection to reinfusion. Autologous CAR T requires collecting each patient's T-cells, shipping them to a limited number of manufacturing sites, engineering and expanding those cells under strict GMP conditions, performing extensive release testing, and then shipping the final product back to the treating center. Each of these steps took time and introduced logistical risk, relying on labor-intensive workflows with long cell-expansion periods and lengthy sterility and potency assays. Because manufacturing capacity was concentrated in only a handful of specialized facilities, bottlenecks were common, and any delays (material shortages, batch failures, weather-related shipping disruptions) extended turn-around times. As a result, early commercial CAR T therapies often required 3–6 weeks or longer from

[8] Foundation for the Accreditation of Cellular Therapy (FACT). *Home – Setting the global standard for high quality patient care in cellular therapies.* Accessed October 28, 2025.
[9] Foundation for the Accreditation of Cellular Therapy (FAC). *Immune Effector Cell Standards.* Accessed November 11, 2025.

leukapheresis to reinfusion, creating significant clinical risk for rapidly progressing patients and contributing to access disparities.[10]

At the same time, the delivery of CAR T therapy was constrained by several connected factors. Infrastructure limitations meant that only transplant and cellular therapy centers possessed the specialized facilities, equipment, and trained staff necessary to support apheresis, cell processing, infusion, and acute complication management, effectively excluding community hospitals from the care pathway.[11] This delay was particularly problematic for patients with aggressive malignancies, which can progress rapidly and render them ineligible for treatment. To manage disease during this waiting period, many patients require bridging therapy.[12] Equally important were issues of reimbursement and financial risk. At the time of FDA approval, payers lacked established frameworks for covering high-cost, one-time therapy treatments. Hospitals were financially vulnerable because existing diagnosis-related groups (DRGs) failed to account for the true costs of CAR T, including not only the product itself but also extended hospitalization, toxicity management, and long-term follow-up. Public and private payers adopted varied and often restrictive coverage policies, generating substantial uncertainty for providers and creating additional barriers for patients seeking access to treatment.[13]

CAR T Present-Day Landscape

Over the past several years, CAR T therapy has moved from an early-stage innovation to a more mature clinical option. While barriers remain, there has been

[10] Sikander Ailawadhi, Leyla Shune, Sandy W. Wong, Yi Lin, Krina Patel, Sundar Jagannath, Optimizing the CAR T-Cell Therapy Experience in Multiple Myeloma: Clinical Pearls From an Expert Roundtable, Clinical Lymphoma Myeloma and Leukemia, Volume 24, Issue 5, 2024.
[11] Mitra A, Barua A, Huang L, Ganguly S, Feng Q, He B. From bench to bedside: the history and progress of CAR T cell therapy. *Front Immunol*. 2023;14:1188049. Published 2023 May 15. doi:10.3389/fimmu.2023.1188049
[12] Lu J, Jiang G. The journey of CAR-T therapy in hematological malignancies. *Molecular Cancer.* 2022;21(1):194. doi:10.1186/s12943-022-01663-0
[13] Association of Community Cancer Centers. *Bringing CAR T-Cell Therapies to Community Oncology.* Washington, DC: Association of Community Cancer Centers; 2025. Accessed October 28, 2025.

meaningful progress in product approvals, clinical practice, patient access, and delivery models. As of 2025, there are seven FDA-approved CAR T-cell therapy products in the United States, with indications spanning multiple hematologic malignancies, including pediatric and young adult B-cell acute lymphoblastic leukemia (ALL), large B-cell lymphomas, mantle cell lymphoma, follicular lymphoma, multiple myeloma, and chronic lymphocytic leukemia / small lymphocytic lymphoma.[14] Building on this foundation, the global CAR T pipeline is expanding rapidly across oncology and beyond, signaling a new era of immune driven treatment. As future CAR T indications broaden beyond hematologic cancers into solid tumors, autoimmune, and inflammatory diseases, the number of eligible patients is expected to increase substantially. This evolution will require a parallel transformation in how CAR T is delivered, reimbursed, and supported across the care continuum.

Improvements in clinical management and delivery infrastructure have allowed CAR T therapy to expand beyond large academic medical centers (AMCs) into select non-transplant academic and community settings. Enhanced understanding of treatment-related toxicities (i.e., CRS and ICANS) and clear patient guidelines have contributed to this shift.[15] The development of standardized grading criteria and clinical algorithms, including the use of the IEC assessment, has strengthened providers' ability to rapidly identify and manage adverse events. These advances have supported the safe introduction of outpatient programs, reducing hospitalization needs and improving patient convenience. [16] CAR T therapies have faced an evolving reimbursement structure that varies for public and private payers. While CAR T is covered by many commercial payers, commercial medical policies determine patient eligibility and out-of-pocket costs. For Medicare, CMS's reimbursement plan has two main components: 1) a bundled payment for inpatient

[14]National Pharmaceutical Council. *The CAR T-Cell Therapy Transformation: Understanding the Technology, Current Landscape, and Future Directions.* Washington, DC: National Pharmaceutical Council; 2025:06. Accessed October 28, 2025.
[15] The University of Texas MD Anderson Cancer Center. IEC Therapy Toxicity Assessment and Management (Cytokine Release Syndrome and Neurotoxicity). Houston, TX: The University of Texas MD Anderson Cancer Center; 2023. Accessed November 11, 2025.
[16] Rejeski K, Subklewe M, Aljurf M, et al. Immune effector cell-associated hematotoxicity: EHA/EBMT consensus grading and best practice recommendations. *Blood*. 2023;142(10):865-877. doi:10.1182/blood.2023020578

services known as a Medicare Severity-Diagnosis Related Group (MS-DRG) and 2) New Technology Add-On Payments (NTAP). In 2021, CMS created the MS-DRG specific to CAR T-cell products (MS-DRG 018). While this was an important first step, the current inpatient payment policy still does not cover the full costs of CAR T therapies, leaving hospitals to bear substantial financial losses. The NTAP provides temporary additional reimbursement for new medical technologies that demonstrate substantial clinical improvement and are not yet fully reflected in existing Medicare Severity Diagnosis Related Group (MS-DRG) payments. NTAP payment is capped at 65 percent, and the MS-DRG 018 frequently falls short in covering expenses depending on hospital billing practices.[17]

Policy and payer frameworks have also evolved alongside clinical and operational progress as CMS recognized CAR T's potential for long-lasting remissions reduces the costs associated with subsequent treatments and hospitalizations. In 2019, CMS issued the National Coverage Determination (NCD) for CAR T, establishing a national framework for Medicare reimbursement of CAR T therapies. CMS recognized that by covering CAR T therapy, there was a potential to reduce overall healthcare costs by providing an alternative to recurrently costly treatments. The NCD confirmed that Medicare would cover FDA approved CAR T therapies when administered in healthcare facilities that meet FDA required safety and reporting standards. Importantly, CMS rejected requiring FACT accreditation as a condition of coverage, setting a critical president that allowed Medicare beneficiaries to receive treatment at any certified location that meets the FDA's requirements. Since then, long-term follow-up studies demonstrate that CAR T can achieve sustained remission of five years or more, reinforcing its potential as a one-time curative treatment. Together, these developments highlight a maturing policy landscape characterized by improved safety, expanding delivery models, and growing recognition of CAR T's transformative potential.

In an effort to urgently drive action, global initiatives like the *CAR T Vision* have called for specific systemic and policy changes to expand access. The multi-stakeholder steering committee emphasizes increasing provider awareness and understanding of

[17] Kamal-Bahl S, Puckett JT, Bagchi I, Miller-Sonet E, Huntington SF. Barriers and solutions to improve access for chimeric antigen receptor therapies. Immunotherapy. Published online May 27, 2022. doi:10.2217/imt-2022-0037

CAR T to improve appropriate referrals. It also focuses on expanding capacity by decentralizing and streamlining care delivery models and demonstrating the long-term impact (and long-term cost mitigation) of CAR T to highlight the need for adequate reimbursement.[18,19] Each of these contribute to the long-term sustainability of CAR T as a treatment option and reinforce the need for a supportive environment to ensure appropriate access.

The CAR T Horizon

Despite nearly a decade of clinical availability, CAR T-cell therapy for blood cancers remains underutilized, with only about two in ten eligible patients ultimately receiving treatment.[20] Bridging this access gap requires a deliberate effort to increase provider and facility networks that are capable of administering CAR T, building off of the existing network of AMCs. A more coordinated, multi-setting model that delivers care closer to patients while maintaining safety and quality standards, will increase essential access.

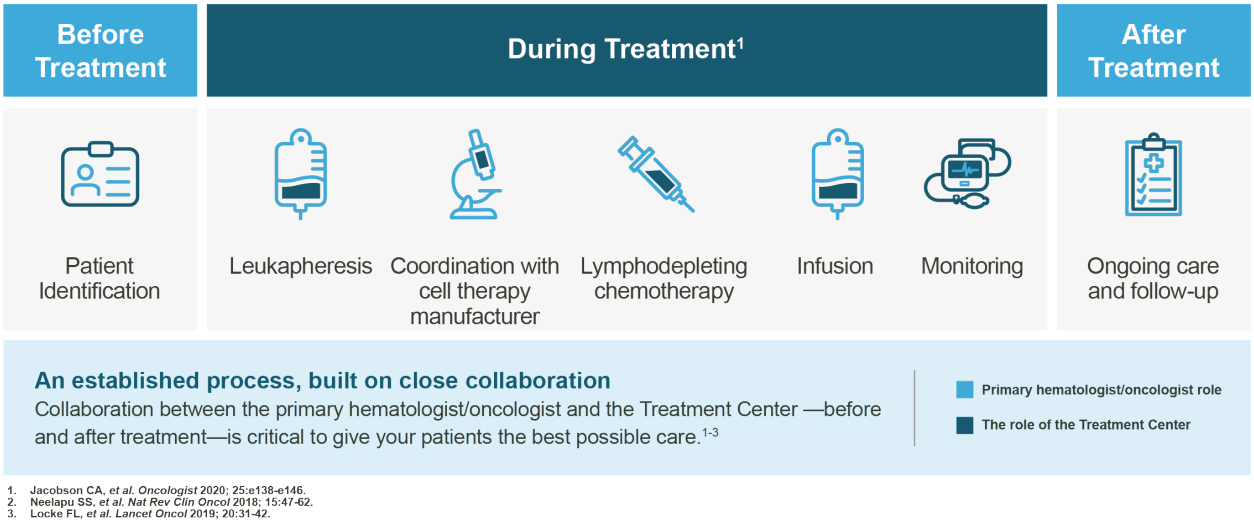
Expanding access will depend on leveraging the strengths of different care settings. AMCs will continue to serve as hubs for research, innovation, and management of the most complex cases. At the same time, qualified community-based programs, when properly resourced and supported with standardized toxicity management protocols and clear referral pathways, can safely deliver CAR T for patients closer to home, reducing geographic and logistical barriers.[21] This approach mirrors models in transplant and specialty oncology, ensuring patients receive care in the most appropriate setting. Delivering CAR T closer to patients in their community helps address the barriers that currently leave many rural and underserved populations

[18] CAR T Vision. *It's Time for CAR T: Doubling patient access by 2030.* 2025. Accessed October 28, 2025.
[19] CAR T Vision. *It's Time for CAR T: Doubling patient access by 2030.* 2025. Accessed October 28, 2025.
[20] Hoffmann MS, Hunter BD, Cobb PW, Varela JC, Munoz J. Overcoming Barriers to Referral for Chimeric Antigen Receptor T Cell Therapy in Patients with Relapsed/Refractory Diffuse Large B Cell Lymphoma. *Transplant Cell Ther*. 2023;29(7):440-448. doi:10.1016/j.jtct.2023.04.003
[21] Yakoub-Agha I, Chabannon C, Bader P, et al. Management of adults and children undergoing chimeric antigen receptor T-cell therapy: best practice recommendations of the European Society for Blood and Marrow Transplantation (EBMT) and the Joint Accreditation Committee of ISCT and EBMT (JACIE). *Haematologica.* 2020;105(2):297-316. doi:10.3324/haematol.2019.229781.

without feasible access. Community-based delivery can reduce the financial, travel, lodging, and caregiving burdens associated with prolonged stays near academic centers. Finally, policy and payment reforms will be critical to sustaining expansion. Coverage frameworks should reward cost-effective delivery across diverse settings while safeguarding quality. Potential levers include site neutral reimbursement, bundled payments, and value-based arrangements that align incentives for providers and payers.[22]

CAR T Patient Journey

The Oncologists and the Treatment Center Play Critical Roles in the CAR T-cell Treatment Journey



[22] IQVIA Institute for Human Data Science. *Achieving CAR T-cell Therapy Health System Readiness: An assessment of barriers and opportunities.* March 20, 2025. Accessed October 28, 2025.

The CAR T therapy pathway is a complex, multi-step process that requires close coordination between patients, providers, caregivers, and payers.[23] The journey generally begins with referral and eligibility assessment, which includes the availability of a full-time caregiver throughout the process. Insurance approval is typically requested as early as possible due to the potential for lengthy delays in the prior authorization process. Once a patient and their doctor decide to move forward, the process of creating the therapy begins with leukapheresis to collect the patient's T-cells. The cells are sent to a specialized manufacturing site where they are genetically engineering to produce the CAR T product, which can vary in time depending on the therapy. Bridging therapy is often used in this waiting period in order to control the disease.[24] Once the engineered cells are returned, patients undergo lymphodepleting chemotherapy to prepare their immune system and ultimately receive the CAR T infusion, a process that takes place over the course of two to seven days. Post-infusion, patients are closely monitored for complications such as CRS and ICANS and must remain geographically close to their treatment center due to the potential rapid onset of adverse events. Patients and their caregivers may be required to make several trips to the treatment center and stay nearby for several weeks to satisfy pre- and post-treatment protocols and procedures. This, in turn, requires a patient to and their full-time caregiver to navigate complex and costly arrangements, such as travel and lodging, food and personal care purchases, potentially extended child, elder, or pet care, household management and time off of work, among other burdens on the patients and their caregiver(s).

> *"CAR T doesn't just affect the patient; it impacts the whole family and the wider community."*
>
> — CAR T Therapy Expert Advisor

[23] Geethakumari PR, Ramasamy DP, Dholaria B, Berdeja J, Kansagra A. Balancing quality, cost, and access during delivery of newer cellular and immunotherapy treatments. Curr Hematol Malig Rep. 2021;16(4):345-356. doi:10.1007/s11899-021-00635-3

[24] Bhaskar ST, Dholaria BR, Sengsayadeth SM, Savani BN, Oluwole OO. Role of bridging therapy during chimeric antigen receptor T-cell therapy. EJHaem. 2021;3(Suppl 1):39-45. doi:10.1002/jha2.335

Timely Access to CAR T is Urgently Needed

Despite the long-term benefits of CAR T, only **2 out of 10 eligible patients** receive this potentially curative therapy.[25] Patients often experience a multitude of obstacles in their CAR T care journey that can block or delay access. Thoughtful system changes to remove these barriers are essential for promoting rapid and timely access to CAR T.

> *"Time toxicity typically refers to any time that is taken up by coordinating, thinking about, travelling to, receiving care, traveling back, managing follow up care, all of that cognitive physical labor that goes into trying to get care for cancer"*
>
> — CAR T Therapy Expert Advisor

Treatment Approval
Delays in referral: Hesitations about patient eligibility criteria and unclear pathways create delays in access and added stress for a patient.[26],[27]
Limited access to specialists: Consultation often requires travel to Centers of Excellence (COEs) primarily located in major cities, which can be financially and logistically burdensome.[28]
Eligibility hurdles: Patients are often required by payers to fail multiple lines of therapy (e.g., chemotherapy) before qualifying for CAR T.
Insurance authorization delays: Prior authorization and PA appeals can take multiple weeks.[29]

[25] CAR T Vision Steering Committee. *Vision for CAR T-cell therapy: Executive Summary — Expanding Availability of CAR T-cell Therapy*. London: CAR T Vision; 2025.
[26] Riedell PA, et al. If They RECUR, You Should Refer: A Community Oncologist Patient ID Roundtable Summary. Transplantation and Cellular Therapy. Accessed November 11, 2025. https://www.astctjournal.org/action/showPdf?pii=S2666-6367%2823%2901642-1
[27] Killmurray C. Community oncology professionals highlight need for more education on immunotherapies. Targeted Oncology. Published August 11, 2021. Accessed November 11, 2025. https://www.targetedonc.com/view/community-oncology-professionals-highlight-need-for-more-education-on-immunotherapies
[28] Mikhael J, Fowler J, Shah N. Chimeric antigen receptor T-cell therapies: barriers and solutions to access. JCO Oncol Pract. 2022;18(12):800-807. doi:10.1200/OP.22.00315
[29] Gajra A, Hime S, Jeune-Smith Y, Feinberg B. Adoption of approved CAR-T therapies among US community hematologists/oncologists. Blood. 2020;136(suppl 1):34-35. doi:10.1182/blood-2020-141990

Financial strain: High out-of-pocket costs due to deductibles, coinsurance, and non-covered services (e.g., travel, lodging, childcare).[30]
Caregiver requirements: Patients must have a full-time caregiver to accompany them throughout the process, which is a major barrier for many.[31]
Logistical complexity: Coordinating travel, accommodations, and caregiver support is often overwhelming. [32]
Emotional stress: Transitioning from community oncology care team can create hesitancy in CAR T therapy decision-making.[33]

CAR T Treatment Administration
Limited treatment centers: CAR T is typically administered at COEs, requiring patients to make multiple trips and stay nearby for extended periods.[34]
Health deterioration risk: Delays in treatment can result in disease progression, making patients ineligible.[35]
Emotional burden: Fear of side effects, uncertainty about outcomes, and being far from home and one's primary support system adds emotional and psychological distress.[36]

[30] Mikhael J, Fowler J, Shah N. Chimeric antigen receptor T-cell therapies: barriers and solutions to access. JCO Oncol Pract. 2022;18(12):800-807. doi:10.1200/OP.22.00315
[31] Kansagra A, et al. Expanding access to chimeric antigen receptor T-cell therapies: challenges and opportunities. Am Soc Clin Oncol Educ Book. 2020;40:e27-e34. doi:10.1200/EDBK_279151
[32] Mikhael J, Fowler J, Shah N. Chimeric antigen receptor T-cell therapies: barriers and solutions to access. JCO Oncol Pract. 2022;18(12):800-807. doi:10.1200/OP.22.00315
[33] Association of Community Cancer Centers (ACCC). Advancing CAR T-Cell Therapy Care Continuity and Collaborative Patient Education. Rockville, MD: Association of Community Cancer Centers; 2023. Accessed November 11, 2025.
[34] Berberabe T. CAR T-Cell Therapy Remains Underutilized, Despite Improvements in Access. *Targeted Oncology.* July 10, 2024. Accessed April 8, 2025.
[35] Ramos KN, Auletta JJ. Receiving CAR T cells gets faster, but not for all in need. Blood Adv. 2025;9(2):436-438. doi:10.1182/bloodadvances.2024015013
[36] Acibadem Healthcare Group. What is the impact of CAR T-cell therapy on mental health? Accessed November 8, 2025.

Post-Treatment Monitoring and Follow-Up
Extended monitoring: Patients may require follow-up for 15 years or more; cancer patients may need lifelong surveillance.
Caregiver responsibilities: There is significant physical, emotional, and mental stress on a caregiver who must provide 24/7 support for the patient during a critical period to monitor for potentially life-threatening side effects.
Side effects: Risks include (but not limited to) cytokine release syndrome, neurotoxicity, and/or infections, and in the long-term, secondary cancers.
Care coordination gaps: Transitioning from COEs to local providers can be fragmented, especially in rural areas.[37]
Data tracking burden: Survivors may be required to submit health data for outcomes-based contracts, which can be costly and complex.
Long-term complications: Survivors may face chronic conditions like post-traumatic stress disorder (PTSD), infertility, organ damage, and/or secondary cancers.[38]

Importantly, patients are not alone in this journey. A caregiver or care partner (at least 18 years of age, often a spouse or family member), must be available 24/7 for at least the first 15 days of the patient receiving treatment. Similar to a care provider, caregivers will need to monitor the patient's side effects, communicate any changes to the patient's condition, and ensure the patient follows the treatment plan. Additionally, caregivers are burdened with the responsibility of coordinating transportation for clinical visits and providing the patient with emotional support. Caregivers, therefore, must often set aside their jobs and other responsibilities which can come with unique financial risk and emotional distress. A patient's health status is linked to the health status of their

[37] Gajra A, Jeune-Smith Y, Kish J, Yeh TC, Hime S, Feinberg B. Perceptions of community hematologists/oncologists on barriers to chimeric antigen receptor T-cell therapy for the treatment of diffuse large B-cell lymphoma. Immunotherapy. 2020;12(10):725-732. doi:10.2217/imt-2020-0118
[38] Ruark J, et al. Patient-reported neuropsychiatric outcomes of long-term survivors after chimeric antigen receptor T-cell therapy. Biol Blood Marrow Transplant. 2020;26(1):34-43.

caregivers, but given the responsibility of caregiver, studies have shown the caregiver's health is also linked to the health of the patient.[39]

> *"So many logistic challenges that patients face in one way or another are illustrative of a financial burden and out-of-pocket costs. If you are away from home for a month, chances are you have a constellation of people helping to care for you. It's not just one plane ticket; it might be ten. It might be paying for parking every day, it might be paying for parking for three people a day as they're rotating so that people can still maintain their jobs and their health insurance"*
>
> — CAR T Therapy Expert Advisor

Improving Timely Access to CAR T-Cell Therapy Access Challenges Through Policy Reform

Despite advances in the delivery and clinical outcomes of CAR T-cell therapy, access remains severely constrained. In addition to the reimbursement challenges and patient and caregiver challenges mentioned above, there are also geographic, logistical, provider, and system-level barriers that prevent most eligible patients from receiving timely care. Despite the many barriers, there are solutions that can be implemented via payer-, provider-, state-, and national-level policy changes. Below are several recommendations outlining the ways in which CAR T-cell therapy can become more widely available. See Appendix A for legislative and regulatory policy options.

Geographic Barriers

CAR T availability remains heavily concentrated in AMCs, creating geographic disparities.[40] Patients living more than 100 miles from a CAR T center have a 30%

[39] Barata A, Hoogland AI, Hyland KA, Otto AK, Kommalapati A, Jayani RV, Irizarry-Arroyo N, Collier A, Rodriguez Y, Welniak TL, Booth-Jones M, Logue J, Small BJ, Jain MD, Reblin M, Locke FL, Jim HSL. Quality of life in caregivers of patients receiving chimeric antigen receptor T-cell therapy. Psychooncology. 2021 Aug;30(8):1294-1301. doi: 10.1002/pon.5674. Epub 2021 Apr 1. PMID: 33739548; PMCID: PMC9828891.

[40] Inserro A. Avalere report looks at geographic challenges to accessing CAR T-cell therapies. *Am J Manag Care.* Published April 16, 2021. Accessed April 8, 2025.

lower likelihood of receiving therapy, and each 10-mile increase in distance reduces the probability of treatment by approximately 6.9%.[41] [42] Regions with fewer than two CAR T centers per 500,000 residents experience the highest rates of underutilization, disproportionately affecting rural and low-socioeconomic communities.[43] Overall, an estimated 77% of eligible patients do not access curative-intent therapies due to logistical and systemic barriers.[44]

Recommendations:

1. Identify and support patients by reducing travel and lodging costs, time away from home, and other associated logistical complexities.
2. Address geographic disparities by expanding the network of authorized treatment centers in areas with limited access.
3. Expand the use of telehealth, remote monitoring capabilities, and shared care models to reduce travel burden, while maintaining safety and quality standards.

Caregiving and Logistical Barriers

Patients must remain near infusion centers for many weeks post infusion to allow for rapid management of CRS and ICANS. This requirement calls for caregiver accompaniment, temporary relocation, and time away from employment. For many,

[41] Ahmed N, Sun F, Teigland C, et al. Chimeric Antigen Receptor T-Cell Access in Patients with Relapsed/Refractory Large B-Cell Lymphoma: Association of Access with Social Determinants of Health and Travel Time to Treatment Centers. *Transplant Cell Ther*. 2024;30(7):714-725. doi:10.1016/j.jtct.2024.04.017

[42] Perez A, Al Sagheer T, Nahas GR and Linhares YPL (2024) Outpatient administration of CAR T-cell therapy: a focused review with recommendations for implementation in community based centers. *Front. Immunol.* 15:1412002. doi: 10.3389/fimmu.2024.1412002

[43] Wu J, Ghobadi A, Maziarz R, et al. Medicare Utilization and Cost Trends for CAR T Cell Therapies Across Settings of Care in the Treatment of Diffuse Large B-Cell Lymphoma. *Adv Ther*. 2024;41(8):3232-3246. doi:10.1007/s12325-024-02917-7

[44] Snider JT, McMorrow D, Song X, Diakun D, Wade SW, Cheng P. Burden of Illness and Treatment Patterns in Second-line Large B-cell Lymphoma. *Clin Ther*. 2022;44(4):521-538. doi:10.1016/j.clinthera.2022.02.004.

paid time off is limited, creating financial and emotional stress.[45] While dedicated lodging support programs alleviate some burden, coverage remains inconsistent. Policies that recognize caregiver costs as part of medical expenses or paid leave programs could improve access.

> *"One CAR T patient, a single young woman whose elderly parents were unable to care for her, had to quickly organize and assemble her own care team."*
>
> — CAR T Therapy Expert Advisor

Providers frequently report delays in evaluation due to long travel distances, limited transportation options, and inability to secure reliable caregivers for post-infusion support, all of which treatment centers must help manage before proceeding with therapy. These barriers create administrative and logistical burdens for providers, who often lack the infrastructure to arrange transportation, lodging, or caregiver support, especially for patients traveling from rural or underserved areas.

Recommendation:

1. Enhance comprehensive support for caregivers to enable confidence in their responsibilities, alleviate distress, and ensure patients are not restricted in access due to a lack of a caregiver.

Provider Level Barriers

Provider level barriers significantly impede timely access to CAR T-cell therapy by limiting the capacity of treatment centers to coordinate evaluation, referral, and delivery of care. Additionally, prior authorization delays from payers force providers to dedicate staff time to navigating complex approval processes, slowing access to care

[45] Hoffmann MS, Hunter BD, Cobb PW, Varela JC, Munoz J. Overcoming Barriers to Referral for Chimeric Antigen Receptor T Cell Therapy in Patients with Relapsed/Refractory Diffuse Large B Cell Lymphoma. Transplant Cell Ther. 2023 Jul;29(7):440-448. doi: 10.1016/j.jtct.2023.04.003. Epub 2023 Apr 7. PMID: 37031747.

and straining clinical operations. A recent study has shown that patients with private insurance can take 2.5 times longer to obtain authorization compared to those with public insurance. Among privately insured patients, those requiring single-case agreements wait a median of 50.5 days versus 19 days for others. [46]

According to a recent ACCC survey of provider needs, many community oncology centers report a lack of infrastructure, training, and staffing necessary to safely deliver CAR T therapy as impediments to establishing care.[47] Establishing facility capacity to meet FDA required safety and reporting standards requires significant investment, such as specialized equipment, enhanced data systems, cell processing partnerships, full-time triage and coordination staff, and experience with ASTCT toxicity management guidelines. In addition, there is a need for increased capacity to support practice administrative operations challenges, such as staff scheduling, patient navigation, and payer issues. Although FDA REMS requirements for CAR T products have been removed, the absence of REMS does not automatically translate into site and provider readiness.

Ensuring safe and high-quality delivery of CAR T-cell therapy governs the establishment of any authorized treatment center, which is directed by FDA guidelines and manufacturer requirements and where formal accreditation is voluntary. While CMS clarified in 2019 that FACT accreditation is not required for Medicare reimbursement of CAR T, many commercial insurers require FACT facility accreditation as a condition of payment. [48] This reimbursement restriction may discourage some cancer care centers from investing in CAR T delivery if they choose not to pursue FACT accreditation. [49]

Even when patients reach treatment centers, provider-level capacity constraints undermine access. Many programs lack formal referral pathways with community oncology practices, resulting in inconsistent referral quality and delayed handoffs. Some referring

[46] Hu B, Vaidya R, Ahmed F, et al. Real-World Analysis of Barriers to Timely Administration of Chimeric Antigen Receptor T Cell (CAR T) Therapy in Diffuse Large B-cell Lymphoma. Transplant Cell Ther. Nov 2024;30(11):1082 e1-1082 e10. doi:10.1016/j.jtct.2024.09.007
[47] Colwell NA, Stearns G. Understanding patient and caregiver concerns during first-line CLL treatment decisions. ACCCBuzz Blog. August 28, 2025. Accessed November 11, 2025.
[48] Koffman B. The best policy to eliminate barriers to care. Cure Today. Published June 22, 2020. Accessed November 11, 2025.
[49] Mikhael J, Fowler J, Shah N. Chimeric antigen receptor T-cell therapies: barriers and solutions to access. JCO Oncol Pract. 2022;18(12):800-807. doi:10.1200/OP.22.00315

clinicians may have limited awareness or understanding of CAR T, which can lead to inappropriate or delayed referrals and ultimately delayed treatment. The lack of standardized processes for patient evaluation and limitation of patient navigation resources further complicate care coordination. Limited access to patient navigation resources uniquely impacts communities of color, who often report worse outcomes in cancer treatment that cannot be explained by clinical differences. A study from the American Cancer Society compared disease characteristics and outcomes of aggressive large B-cell lymphoma for white patients and patients of color in a clinic with a dedicated nurse navigator program, finding that patients of color were more likely to utilize nurse navigator resources, suggesting a higher degree of barriers to care, compared to white patients. The study found that access to dedicated nurse navigators improved outcomes, resulting in equitable clinical outcomes among white patients and patients of color.[50] Moreover, financial and operational risk, such as the need to manage patient financial challenges, secure payer approvals, and ensure continuity of caregiver support, places additional strain on providers, who may delay or decline CAR T referrals due to resource limitations. Ultimately, these provider-level barriers collectively restrict treatment capacity, perpetuate inequities, and delay life-saving therapy for eligible patients.

System Level Barriers

Recommendations:

1. Remove or simplify prior authorization requirements and processes and ensure comprehensive coverage and adequate reimbursement for CAR T-cell therapy and related services at an authorized treatment center.
2. Reduce financial risk for cancer care practices to support investment in the necessary infrastructure, staffing, and training to safely deliver CAR T.

[50] Bei, H. et al. Equal access to care and nurse navigation leads to equitable outcomes for minorities with aggressive large B-cell lymphoma. American Cancer Society Journal. Published July 21, 2021.

System-level barriers to CAR T-cell therapy reflect broader structural limitations across the US healthcare delivery and payment system that impede timely access and equitable availability of care. One of the most significant bottlenecks occurs between eligibility determination and treatment initiation, where delays are driven by disjointed referral systems, insufficient treatment site capacity, and payer fragmentation across states and insurance markets. The limited number of authorized treatment centers which are primarily concentrated in large academic medical centers creates geographic access barriers for patients who must travel long distances for evaluation, leukapheresis, infusion, and follow-up. This centralization also strains existing sites, leading to long waitlists and scheduling delays. These delays can be clinically significant in aggressive hematologic malignancies where patients may deteriorate before treatment.

> *"Site of care really does matter in terms of exacerbating that financial and psychological distress for patients and caregivers after therapy"*
>
> — CAR T Therapy Expert Advisor

> *"We would hope to improve the prior authorization process to the point that people aren't just getting denied on the outset"*
>
> — CAR T Therapy Expert Advisor

Another systemic issue is the lack of scalable infrastructure and care models that connect community oncology practices with CAR T centers. The healthcare system is not yet configured to support decentralized delivery through shared care or hub-and-spoke networks.[51] Important pretreatment steps such as laboratory evaluations, imaging, bridging therapy, or even leukapheresis, are often restricted to tertiary centers rather than distributed across community sites. This not only reduces efficiency but increases cost and patient burden. The growing call for expansion of outpatient CAR T administration and remote monitoring capabilities highlights gaps in system capacity.

[51] Bishop MR, Kay GE. CAR T-cell therapy: a collaboration between authorized treatment centers and community oncologists. Semin Oncol. 2024;51(3-4):87-94. doi:10.1053/j.seminoncol.2024.02.001

These are not simply clinical innovations, but they are responses to structural bottlenecks that limit throughput and drive inequities in care. Similarly, telehealth adoption for evaluation and follow-up remains inconsistent due to variable reimbursement policies, cross-state licensure restrictions, and technology gaps, reflecting another system-level failure to modernize care delivery.

> *"Telehealth really does help extend the provider to the patient without them having to drive all the way in"*
>
> — CAR T Therapy Expert Advisor

Recommendations:

1. Enable the delivery of safe and quality CAR T through innovative reimbursement reforms and provider licensure pathways aimed at advancing patient-centered care.
2. Establish formal referral pathways and processes between referring community cancer programs and authorized CAR T-cell therapy treatment centers.
3. Modernize data collection, evaluation, and payment systems to facilitate the adoption of advanced therapies, like CAR T.

Conclusion

CAR T therapy represents a transformative advance in cancer care, offering the potential for durable remission and even cure for patients with otherwise limited options. Yet, systemic, financial, and logistical barriers continue to restrict access for many eligible patients. Addressing these challenges requires coordinated policy action to expand treatment capacity, modernize reimbursement frameworks, and provide comprehensive patient and caregiver support. By implementing evidence-driven reforms and investing in infrastructure, stakeholders can ensure that CAR T therapy fulfills its promise as a sustainable, equitable, and life-saving treatment for all who need it.

Appendix A

Policy Options: The following policy options outline potential federal and state approaches across four categories – Patient and Caregiver Support, Coverage and Payment, Increasing Delivery Capacity, and Data and Systems – in attempt to increase access to CAR T-cell therapies. These options, taken individually and/or grouped, aim to address the current unmet needs across a multitude of barriers hindering stakeholders including, but not limited to patients, caregivers, and providers. Given this is an actively evolving space, this list is not all-encompassing.

Patient and Caregiver Support: *The following policy options overview federal and state approaches to ease the burden of CAR T-cell therapy on patients and caregivers, ranging from travel and support benefits to caregiver education and reimbursement frameworks.*

Patient and Caregiver Support	
Policy Option: Guarantee Travel and Support Benefits	
Details	Establish state or federally funded travel and lodging support programs that cover patient and caregiver transportation, temporary housing, and paid leave during the post-treatment monitoring period.
Approach	**Federal:** Medicare demonstration projects (eg similar to CGT Access Model); targeted tax credits **State:** Medicaid waivers; pass a law to cover non-emergency medical transportation; provide advanced payment of direct booking, authorize paid home health aid/caregiver support during post-infusion monitoring
Policy Option: Standardize OIG Definitions for Travel and Lodging Associated with Patient Care	
Details	Encourage the OIG to expand on the advisory opinions from 2024 and 2025 defining patient travel and lodging coverage definitions.

Approach	**Federal:** OIG Advisory Opinions approving financial assistance for qualifying patients, covering round-trip airfare or ground transportation, lodging at a modest hotel, and up to a daily amount for meals and other expenses like parking. Key requirements may include a certain distance from the treatment center, a specific income level, and no other insurance coverage for these costs. **State:** N/A
Policy Option: Establish Paid Caregiver Support and Job Protection Programs	
Details	Expand Family and Medical Leave Act (FMLA) eligibility and create a federally funded "caregiver leave" benefit for CAR-T caregivers, allowing partial wage replacement and job protection during the post treatment monitoring period.
Approach	**Federal:** Pass a law to expand FMLA to create federally funded caregiver leave **State:** Medicaid waivers; Pass law for caregiver tax credits for lost income/insurance disruptions
Policy Option: Develop Standardized Caregiver Education and Certification Programs	
Details	Provide structured caregiver education and training covering symptom monitoring, neurotoxicity awareness, and emergency response before discharge.
Approach	**Federal:** Participate in CMS CPT/HCPCS code development process, then issue guidance or a bulletin on their use in Medicare and Medicaid **State:** Medicaid waivers, Pass law for hospitals, or county public health organizations to offer the training
Policy Option: Establish a Caregiver Reimbursement Framework for CAR T Patients	
Details	Establish a caregiver reimbursement framework; allow public and private payers to recognize caregiver costs such as lodging, travel, and lost wages as reimbursable medical expenses tied to CAR-T treatment.

Approach	**Federal:** CMS demonstration model; federal tax credit or direct stipend program modeled after the VA's caregiver assistance initiative; private payer mandates requiring insurers to cover caregiver-related expenses as medically necessary support services; update OIG anti-kickback statute guidance to allow caregiver support as part of patient support programs **State:** Medicaid waivers	
<u>Policy Option:</u> Expand Patient- and Caregiver-related HCPCS Codes		
Details	Develop enhanced Principal Illness Navigation (PIN) codes for CAR T, focusing on cross-center coordination to reduce "time-toxicity" from fragmented scheduling, travel planning, and post-treatment follow-up.	Establish a CAR T specific navigation code would support reimbursement for the unique patient care coordination activities required before, during and after therapy.
Approach	**Federal:** Participate in CMS CPT/HCPCS code development process, then issue guidance or a bulletin on their use in Medicare and Medicaid	**State:** Medicaid waiver or state demonstration
<u>Policy Option:</u> Patient and Nurse Care Navigation		
Details	Enable better utilization or adaptation of the principal care navigation, principal care management , other relevant HCPCS codes.	
Approach	**Federal/State:** Promote availability of CPT codes to bill for care navigation services for Federal payers; encourage adoption by commercial payers	

Coverage and Reimbursement: *The following policy options overview federal and state approaches to ease the burden of coverage and reimbursement issues within the CAR T-cell therapy space.*

Coverage and Reimbursement		
Policy Option: Telehealth/Home-Based Care Reimbursement		
Details	Reimburse virtual or home visits for pre-treatment evaluations, post-infusion check-ins, symptom monitoring, wearable devices.	
Approach	**Federal:** CMS demonstration, Expand CMS telehealth reimbursement codes; Increase awareness of codes/educate providers on availability and appropriate use **State:** Medicaid waivers, pass a law	
Policy Option: Streamline Prior Authorization and Coverage Timelines		
Details	Require Medicare and Medicaid plans to publicly report prior authorization timelines, approval rates, and average reimbursement lag times for CAR T therapy.	Require Medicare and Medicaid plans to approve or deny CAR T coverage requests within 72 hours and 24 hours for urgent cases and require the establishment of a transparent and expedited appeals process, with peer review by an oncologist experienced in CAR T.
Approach	**Federal:** Mirror language/requirements in existing regulations (e.g. 2024 PA/interoperability FR), then issue a Medicaid bulletin on how states can adopt this practice	**State:** Pass legislation impacting state Medicaid, fully insured commercial plans, and their respective individual marketplace plans

Policy Option: Establish A Physician Gold Carding Program	
Details	Mandate commercial health plans and Medicare plans to evaluate a provider's history of prior authorization requests, including the administration of CAR T and its support services. If a provider's requests meet or exceed a certain approval rate threshold for a specific service over a defined period, they are granted "gold card" status.
Approach	**Federal:** Pass legislation impacting commercial, Medicare, and Medicaid **State:** Pass legislation impacting fully insured, state Medicaid, and/or the individual marketplace plans
Policy Option: Develop Standardized Caregiver Education and Certification Programs	
Details	Provide structured caregiver education and training covering symptom monitoring, neurotoxicity awareness, and emergency response before discharge.
Approach	**Federal:** Participate in CMS CPT/HCPCS code development process, then issue guidance or a bulletin on their use in Medicare and Medicaid **State:** Medicaid waivers, Pass law for hospitals, or county public health organizations to offer the training
Policy Option: Ban Alternative Funding Programs for CAR T Therapies	
Details	Issuing a new provision, similar to §156.122(g) proposed in the Alternative Task Force letter. The proposed provision states, that "a health plan cannot require an enrollee to apply for or enroll in, a third-party assistance program including, but not limited to, manufacturer copay assistance, manufacturer patient assistance programs, charitable funds, or any other third-party entity, as a prerequisite for an enrollee receiving a coverage determination; requesting access through an exceptions process; or initiating an appeal."

Approach	**Federal:** Issue a new rule under the Affordable Care Act (ACA), or issue a new rule under the NBPP **State:** Pass legislation prohibiting the use of AFPs that also directs the state AG's to go after these programs in fully insurance plans, including employer plans and individual marketplace plans
Policy Option: Ensure Parity Within Medicare Advantage Plans	
Details	CMS should investigate and correct coverage inconsistencies between Medicare and MA plans when providing review and oversight each new coverage year.
Approach	**Federal:** CMS rulemaking; CMS direct outreach to plans through plan liaisons; OIG reports **State:** N/A
Policy Option: Ensure Adequate Provider Reimbursement for Government Payers	
Details	Ensure providers are appropriately reimbursed across Medicare and Medicaid in line with commercial payments.
Approach	**Federal:** MS guidance clarifying that MA plans must adhere to the NCD established by CMS; Advocate to CMS (via IPPS rulemaking cycle) for increased reimbursement of MS-DRG 018 **State:** N/A
Policy Option: Unbundle Payments Made in CAR T Journey	
Details	Offer separate payments to cover the hospital's cost of acquiring and administering the drug product.
Approach	**Federal:** Create separate reimbursement codes for each service delivered (e.g., drug acquisition, leukapheresis, bridging therapy) **State:** N/A

Increasing Delivery Capacity: *The following policy options overview federal and state approaches to expand access to CAR T-cell therapies via various care coordination and incentive tactics.*

Increasing Delivery Capacity		
Policy Option: Support Interstate Telehealth and Cross-State Care Coordination		
Details	Enable provisional or reciprocal enrollment of qualified CAR T treatment centers across state lines to facilitate patient access when no in-state option exists.	Remove interstate licensure barriers for oncology and transplant specialists. providing telehealth consults, follow-up visits, and caregiver training.
	Make permanent the telehealth flexibility in Medicare allowed during the pandemic	Incentivize states to join interstate compacts for CAR T related telemedicine to reduce travel time and speed referral pathways.
Approach	**Federal:** Pass a law to make flexibilities permanent, CMS demonstration model	**State:** Interstate licensure compacts require state Medicaid agencies to expedite provider enrollment for CAR-T treatment cases
Policy Option: Create Financial Incentives for CAR-T Facility Accreditation		
Details	Create financial incentives for hospitals and community oncology centers to obtain quality accreditation for CAR T therapy.	
Approach	**Federal:** HHS tax credits or grants for facilities that achieve accreditation through the Foundation for the Accreditation of Cellular Therapy (FACT) or an equivalent standard; enhanced Medicare reimbursement rates or bonus payments for newly accredited centers that administer CAR-T therapies within approved safety protocols; low-interest federal loans to support capital investments in equipment, staffing, and facility modifications required for certification. **State:** Pass legislation to create tax credits or grants for facilities that achieve accreditation through FACT or an equivalent standard	

<u>Policy Option:</u> Simplify Out of State Provider Enrollment and Reciprocity		
Details	Enable provisional or reciprocal enrollment of qualified CAR-T treatment centers across state lines to facilitate patient access when no in-state option exists.	Allow cross-state access so patients can receive CAR-T treatment closer to home
Approach	**Federal:** CMS rulemaking on Medicaid provider enrollment, then issue a Medicaid bulletin on how states facilitate its use	**State:** Interstate licensure compacts; CMS rulemaking to require Medicaid programs to expedite provider enrollment processes
<u>Policy Option:</u> Establish an Access to American Innovation Federal CAR T Care Initiative		
Details	HHS could launch a national grant or demonstration program focused on improving CAR-T access among certain populations, including patients from rural areas, racial/ethnic minority groups, and low-income households. Grants would fund navigation, caregiver support, and telehealth infrastructure.	Establish a federal "Advanced Cell Therapy Access Fund" to reimburse high-cost CAR T therapies under conditional coverage.
Approach	**Federal:** HHS grant program	**State:** N/A

Data and Systems: *The following policy options overview federal and state approaches to expand access to modernize and standardize the data components necessary for access to and success of CAR T-cell therapy.*

Data and Systems			
<u>Policy Option:</u> Modernize Long-Term Follow-Up (LTFU)			
Details	Direct FDA to move from a one-size-fits-all 15-year requirement to a risk -tiered, patient centered LTFU framework that preserves safety while cutting burden and attrition. Align durations and intensity with product risk Consider tired or risk-based LTFU durations based on patient condition, therapy type, and time since treatment. Consider adaptive regulatory pathways that allow for evolving LTFU protocols based on real-world evidence.		
Approach	**Federal:** FDA rulemaking or program guidance on LTFU framework **State:** N/A		
<u>Policy Option:</u> Develop a Standardized National Referral Network for CAR-T Therapy			
Details	Establish a centralized referral system linking community oncologists to accredited CAR-T centers.		
Approach	**Federal:** National Cancer Institute or CMS registry, then issue a Medicaid bulletin on how states can join or facilitate its use **State:** Interstate agreements/compacts for cross-state referrals, likely via state Medicaid programs		
<u>Policy Option:</u> Integrate Time-to-Treatment Benchmarks into CAR-T Coverage Standards			
Details	Established a quality measure that specifies maximum timelines for referral, authorization, leukapheresis, and infusion	Within CAR-T standards of care or care protocols, include maximum timelines for referral, authorization, leukapheresis, and infusions	CMS could monitor adherence through reporting tied to quality incentives

Approach	**Federal:** After a quality measure is established, encourage CMS rulemaking on maximum treatment timelines, then issue a Medicaid bulletin on how states facilitate its use	**State:** After a quality measure is established, propose legislation or rulemaking on timelines to be added to hospital benchmarking metrics	**Other:** Provider associations/patient advocacy groups, etc, will be needed in the creation and adoption of a quality measure - establishing a maximum treatment timelines as part of CAR-T standards of care
<u>Policy Option:</u> Create a National CAR T Registry			
Details	Track outcomes, safety, and costs across treatment centers. The data would provide real-world evidence to support increased reimbursement and more flexible payment models.		
Approach	**Federal:** Tracking could be established via CMS, or via national group **State:** N/A		