CAR T-Cell Therapies: Uptake Challenges and Opportunities to Improve Access

Overview

Chimeric antigen receptor T-cell (CAR T-cell; CAR-T) therapy is a type of immunotherapy that utilizes a patient's T-cells to treat various diseases. CAR T-cell therapies have significantly transformed treatment in the oncology space, achieving high response and remission rates. A robust pipeline offers the potential to expand CAR T-cell therapy treatments to a broader range of patients with oncology and non-oncology diagnoses.

Despite their high rate of effectiveness, including life extension and disease remission, uptake of CAR T-cell therapies has been low, likely due to reimbursement and infrastructure challenges that restrict access to treatment. A claims analysis of 6 CAR T-cell therapies approved and available in the U.S. through 2023 was conducted to understand eligibility and uptake rates across patient demographics. The results showed:

- Only 10% of clinically eligible Medicare fee-for-service (FFS) patients received CAR T-cell therapy for an approved indication
- Average time from initial diagnosis to receipt of a CAR T-cell therapy was approximately 29 months (median 21 months)
- Women, racial minorities, and patients living in the South and West were treated at lower rates relative to eligibility
- CAR T-cell therapy treatment of eligible patients residing in rural areas was low (9.1%)

To improve the uptake of these lifesaving therapies, healthcare stakeholders must collaborate to remove barriers to accessing treatment, including advocating for appropriate reimbursement, strengthening site-of-care networks, and increasing early patient identification and education to enhance understanding of the value of CAR T-cell therapies.

The CAR T-Cell Treatment Landscape: Today and Tomorrow

CAR T-cell therapy is a personalized cancer treatment that engineers a patient's T-cells to recognize a specific antigen on cancer cells, prompting the immune system to attack and destroy the cells. This process involves extracting a patient's T-cells, modifying them to express chimeric antigen receptors, and reinfusing them back into the patient.[1] There are currently 7 FDA-approved CAR T-cell therapies available in the U.S., primarily targeting hematologic malignancies. The analysis includes all those approved and marketed before 2024 (Table 1).

CAR T-cell therapy innovation is rapidly evolving. As of August 2025, approximately 2,140 CAR T-cell therapy clinical trials were registered on ClinicalTrials.gov. Robust research activity is poised to expand CAR T-cell therapy further into treating oncology and non-oncology indications (e.g., diseases like systemic lupus erythematosus, rheumatoid arthritis, myasthenia gravis, eosinophilic asthma, and other fibrotic conditions) and could provide treatment options to millions of patients worldwide.[2]

The CAR T-Cell Treatment Landscape: Today and Tomorrow

While the availability of CAR T-cell therapies is increasing, access challenges persist. Site of care restrictions, inadequate reimbursement, payer coverage challenges, and other barriers have hindered the meaningful uptake of these therapies, limiting their potential to transform patient outcomes.

Table 1. CAR T-cell Therapies Available in the U.S.[a] Prior to 2024

Brand	Generic Name	Indication(s)	FDA Approval
Abecma	Idecabtagene vicleucel	Multiple Myeloma (MM)	March 2021
Breyanzi	Lisocabtagene maraleucel	Diffuse Large B-Cell Lymphoma (DLBCL) Follicular Lymphoma Grade 3B (FL3B)[b]	DLBCL/FL3B: February 2021 Second-Line (2L) DLBCL/FL3B: June 2022
Carvykti	Ciltacabtagene autoleucel	MM	February 2022
Kymriah	Tisagenlecleucel	DLBCL Follicular Lymphoma (FL)[c]	DLBCL: May 2018 FL: May 2022
Tecartus	Brexucabtagene autoleucel	Mantle Cell Lymphoma (MCL) B-Cell Precursor Acute Lymphoblastic Leukemia (B-ALL)	MCL: July 2020 B-ALL: October 2021
Yescarta	Axicabtagene ciloleucel	DLBCL FL	DLBCL: October 2017; 2L: April 2022 FL: April 2021

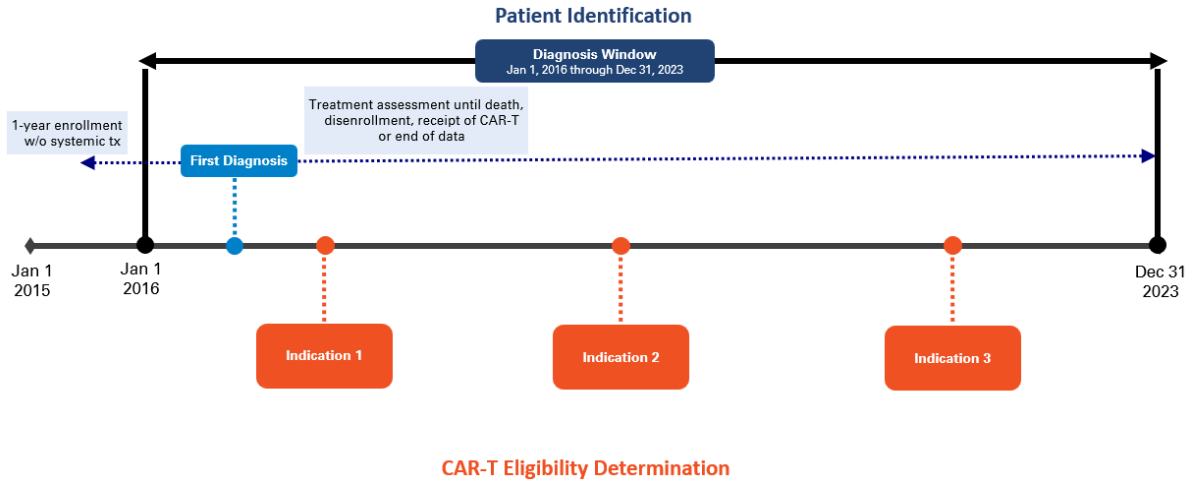
[a] Aucatzyl was approved by the FDA in 2024 for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Not included in this analysis.
[b] Approved for FL, MCL, and chronic lymphocytic leukemia/small lymphocytic lymphoma after end of study period.
[c] Approved for B-ALL in pediatric patients. Not included in this analysis.

Disparities in CAR T-Cell Uptake and Utilization in the Medicare FFS Population

To assess CAR T-cell therapy utilization and uptake, a retrospective claims database study analyzed Medicare FFS beneficiaries from 2016 to 2023. The analysis identified systemic therapies of interest (e.g., immunotherapies, chemotherapies, and CAR T-cell therapies) included in the National Comprehensive Cancer Network (NCCN) guidelines. Approved indications and systemic therapies were then mapped to relevant diagnosis and procedural codes to define patient cohorts for the 6 available CAR T-cell therapy treatments. Inclusion/exclusion criteria were applied to the CAR T-cell therapy cohorts (e.g., continuous enrollment in Medicare, age at diagnosis) to identify patients eligible for CAR T-cell therapy and, among them, those who received treatment (Figure 1).

CAR T-cell Therapy Uptake Varies by Patient Demographics: The average age of Medicare FFS patients eligible for CAR T-cell therapy was 73.6 years (median, 73.0 years), whereas the average age of treated patients was slightly lower (70.8 years; median, 71.0 years). Males comprised 54.0% of eligible patients and 59.7% of those treated – this represented higher eligibility and significantly higher treatment rates than observed in females. Racial minority patients (i.e., Black, Asian, Hispanic, and North American Native) had lower CAR T-cell therapy treatment rates relative to eligibility, with Black patients most underrepresented (4.2% eligible vs 3.0% treated). This trend may be attributed to several sociodemographic factors, including inadequate supplemental insurance coverage or receiving care at under-resourced facilities that lack innovative forms of treatment and robust patient financial support (Table 2).[3]

Figure 1. Example Cohort: Drug A



Regionally, patients in the Northeast had higher CAR T-cell therapy treatment rates relative to eligibility (23.3% eligible vs 27.4% treated) compared to the South (34.6% eligible vs 31.7% treated) and West (20.0% eligible vs 18.2% treated), possibly due to demographic factors like age, distance to a treatment center, income, and educational attainment (see Table 2). Just over 9% of patients living in rural areas received CAR T-cell therapy, compared to 10.3% of patients in urban areas (see Table 2).

Table 2. CAR T-Cell FFS Medicare Population Demographics, 2016–2023

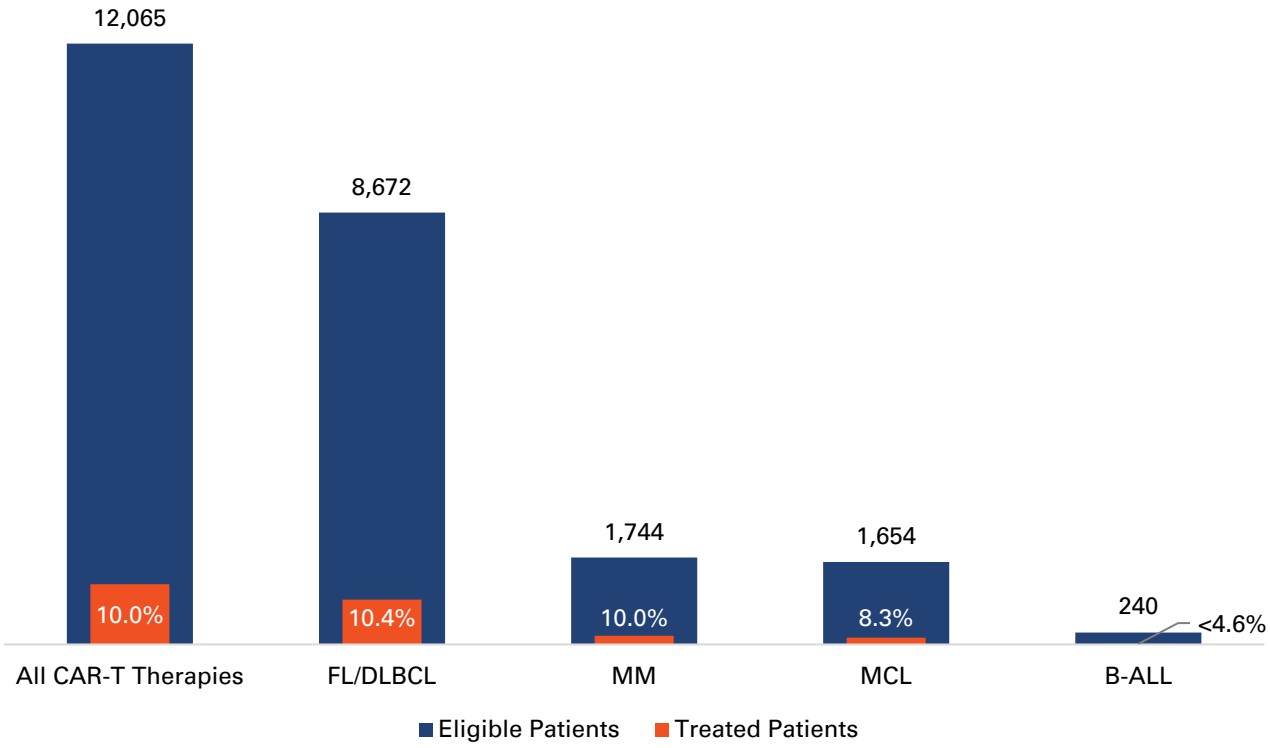
		Eligible (N=12,065)		Treated (N=1,210)	
Age at Index	Mean (SD)	73.6	7.6	70.8	6.4
	Median (Q1, Q3)	73	69, 78	71	68, 74
	Min (Max)	21	99	27	87
Sex, n (%)	Female	5,551	46.0%	488	40.3%
	Male	6,514	54.0%	722	59.7%
Race, n (%)	White	10,624	88.1%	1,071	88.5%
	Black	506	4.2%	36	3.0%
	Asian	214	1.8%	19	1.6%
	Hispanic	168	1.4%	16	1.3%
	North American Native	26	0.2%	0	0.0%
	Other/Unknown	527	4.4%	68	5.6%
Region,[a] n (%)	Northeast	2,809	23.3%	331	27.4%
	Midwest	2,676	22.2%	276	22.8%
	South	4,169	34.6%	383	31.7%
	West	2,410	20.0%	220	18.2%
Urban/Rural,[a] n (%)	Urban	9,456	78.4%	972	80.3%
	Rural	2,608	21.6%	238	19.7%
Age at CAR T-Cell Treatment	Mean (SD)			73.2	6.4
	Median (Q1, Q3)			73.5	70, 77
	Min (Max)			32	88
Days From Index Date to CAR T-Cell	Mean (SD)			874.5	664.6
	Median (Q1, Q3)			632	339, 1,314
	Min (Max)			43	2,834

[a] Analysis includes the 50 U.S. states and DC.

Disparities in CAR-T Uptake and Utilization in the Medicare FFS Population (cont)

CAR T-Cell Therapy Utilization Ranges Across Approved Indications: Overall uptake across all CAR T-cell therapies was low, with 10.0% of eligible patients receiving treatment. Uptake varied by indication, with MCL and B-ALL having the lowest rates (8.3% and 4.6%, respectively). Uptake for these 2 conditions could be lower for clinical reasons: 60% to 80% of adults with B-ALL achieve remission from early lines of therapy, and immunotherapy like CAR T-cell therapy is reserved for patients who are refractory or relapsed.[4] In MCL, diagnosis frequently occurs in stages 3 or 4,[5] which could decrease the number of patients healthy enough to receive CAR T-cell therapy after other treatments fail.

Figure 2. Proportion of CAR T-Cell Eligible Patients Receiving CAR T-Cell Treatment



Effects of Delayed CAR T-Cell Therapy Access on Quality of Life and Survival

Compared to traditional cancer treatments, such as surgical resection, radiotherapy, or chemotherapy, CAR T-cell therapies can sustain longer remissions, cause fewer side effects, and enhance the patient's quality of life through shorter treatment times and faster recovery.[6] However, delays in access can worsen a patient's prognosis. For example, one study demonstrated that a 2-month reduction in wait time resulted in a 3.3% increase in patient survival and a more than 10% increase in the number of eligible patients receiving CAR T-cell therapies.[7] A survey of community oncologists found that 65% of CAR T-cell therapy candidates deteriorated prior to treatment, underscoring the importance of early patient identification and effective communication between providers, CAR T-cell therapy treatment centers, and manufacturers.[8-10]

Effects of Delayed CAR-T Access on Quality of Life and Survival (cont)

CAR T-cell therapies have been transformational in oncology, introducing a curative potential through immune reprogramming and achieving durable responses in patients. For example, CAR T-cell therapies have generated complete response rates between 71% and 81% in multicenter clinical trials for patients with B-ALL and overall response rates between 73% and 98% in patients with MM.[11] Pipeline products are poised to further transform care for other indications, such as solid tumors (e.g., gastric and pancreatic cancers) and autoimmune diseases (e.g., systemic lupus erythematosus).[12] Overall, timely CAR T-cell therapy access could boost survival by 3% to 5% for every month that treatment is not delayed, extending both the quality of life and survival for current and future patients.[13]

Why Are Eligible Patients Unable to Access CAR-T in a Timely Manner?

Despite their clinical efficacy and patient eligibility, CAR T-cell therapies continue to have low uptake. This could be due to the limited number of treatment sites, low payment rates, and payer coverage restrictions.

Site Limitations: Currently, only 159 sites across the U.S. are accredited to administer CAR T-cell therapies, and most are in urban areas.[14,15] Transportation barriers, distance to treatment sites, and travel costs (e.g., food, lodging, gas) may be prohibitive to patients. Eighty-five percent of patients with cancer are treated by community oncologists; these patients may experience challenges accessing CAR T-cell therapy - accredited sites, highlighting the need for more accredited CAR T-cell therapy administration sites, including in community oncology offices. Identified and perceived difficulties in travel for treatment and follow-up care for rural patients may influence providers' decisions around a patient's course of treatment.[16]

Reimbursement Challenges: Medicare's Inpatient Prospective Payment System (IPPS) inadequately reimburses hospitals for costs incurred while administering CAR T-cell treatments, leading to financial losses. Medicare Severity Diagnosis-Related Group (MS-DRG) 018 was implemented in 2021 and provides a bundled payment to reimburse hospitals for all expenses related to the acquisition and administration of CAR T-cell immunotherapies.[17] However, assigning a single code to a group of diverse products that vary widely by clinical indication, patient preparation, manufacturing time and processes, and adverse events is inadequate to ensure appropriate reimbursement for all products in the MS-DRG. While New Technology Add-On Payments (NTAPs) provide temporary supplements and are a percentage-based payment based on the cost of the new service or the amount by which the costs of the case exceed the standard DRG payment, whichever is less—65% for eligible CAR T-cell therapies (vs 75% for eligible sickle cell gene therapies)[18]—NTAPs are only granted for a maximum of 3 years, and not every CAR T-cell therapy is assured of being eligible for an NTAP.[19] Following NTAP expiration, there is no guarantee of novel MS-DRG creation to minimize hospital losses and incentivize the use of products.

Why Are Eligible Patients Unable to Access CAR-T in a Timely Manner? (cont)

Outpatient reimbursement represents an opportunity to increase CAR T-cell therapy uptake and decrease associated costs. In one study, the outpatient administration of CAR T-cell therapy was associated with a 40.4% reduction in total costs compared to inpatient administration, resulting in a savings of nearly $33,000 per patient.[20] Despite this potential for savings, the Centers for Medicare & Medicaid Services' (CMS') 3-Day Payment Window discourages outpatient administration by bundling reimbursement for outpatient services into the IPPS rate if a related hospital admission occurs within 3 days of the outpatient procedure.[21] The resulting financial loss for the administering outpatient provider may deter outpatient CAR T-cell therapy administration, as a patient admission following outpatient administration would be costly for the administering provider and patient. Changes are needed to existing reimbursement policies to encourage outpatient administration as a viable, cost-effective option.

Coverage Delays and Restrictions: Patients with insurance other than FFS Medicare (e.g., Medicare Advantage, private commercial coverage) may encounter delays and barriers to accessing CAR T-cell therapies. One study reported that U.S. health plans applied access restrictions in about 67% of their cell and gene therapy coverage policies, with varying levels of access restrictions and consistency.[22] A review of the health plans included in the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) database revealed that these plans issued 109 coverage policies for the 6 cell therapies reviewed, and overall applied coverage restrictions in 64% of their decisions.[23] Health plans may also include narrow provider networks that exclude certain providers and/or sites of care, further limiting the already restricted options patients have for inpatient CAR T-cell therapy administration.[24]

How Can the U.S. Ensure Patients Who Could Benefit from CAR-T Receive Treatment?

To improve access to lifesaving CAR T-cell therapies, stakeholders across the healthcare landscape should consider modifying reimbursement mechanisms and treatment infrastructure to incentivize their adoption. Solutions could include:

Evolving CMS Reimbursement of CAR T-Cell Therapies: CMS could update payment mechanisms to approximate the actual costs of CAR T-cell therapies and their associated procedures more closely, including:

- Increasing the once-a-year frequency with which all NTAPs are granted to bolster uptake
- Ensuring that all CAR T-cell therapies qualify for an NTAP, and increasing the add-on payment amount (i.e., minimum add-on of 75% of the product acquisition cost)
- Efficiently creating and updating reimbursement mechanisms that appropriately balance adequate payment and patient access considerations
- Ensuring CMS pays an adequate amount for each step of the CAR T-cell therapy administration process (e.g., leukapheresis, preparation of the CAR T-cell therapies)
- Facilitating outpatient administration of CAR T-cell therapies by creating an exception to CMS' 3-Day Payment Window that establishes a new ambulatory payment classification (APC) for CAR T-cell therapy administration in the Outpatient Prospective Payment System (OPPS).

How Can the U.S. Ensure Patients Who Could Benefit from CAR-T Receive Treatment? (cont)

Expanding the CAR T-Cell Therapy Provider Network: State and government agencies could offer grants and other incentives to rural and/or underserved providers to train their staff and build infrastructure for CAR T-cell therapy administration, providing patients with site-of-care options that are accessible and reduce travel burdens.

Optimizing Referrals and Increasing Outpatient Capacity: Early recognition of potential CAR T-cell therapy patients and provider-patient-caregiver discussions around CAR T-cell therapy during initial stages of treatment can improve time to decision-making, resulting in decreased treatment delays and healthier patients receiving CAR T-cell therapies.

Creating and Expanding Services for Patients and Caregivers: Travel assistance would be a valuable benefit for insurers to offer, alleviating one significant hurdle for patients and caregivers. Education and benefits for caregivers could improve decision-making, access, and outcomes.

Conclusions

The promise of CAR T-cell therapies and other innovative therapies cannot be realized until clinical, administrative, access, and reimbursement barriers are addressed through the combined efforts of stakeholders along the care journey. More patients stand to benefit from CAR T-cell therapy and other transformative therapies than can currently access them, and this issue is likely to worsen as cost pressures continue in the healthcare space.

Methodology

A retrospective claims database study using Medicare administrative data was conducted to evaluate the CAR T-cell therapy uptake rate in the Medicare FFS population from 2016 to 2023. CAR T-cell therapies approved after this period, such as Aucatzyl, which was approved in November 2024 for relapsed/refractory B-cell precursor ALL, are not included in this analysis. Systemic therapies of interest (chemo- and immunotherapy, CAR T-cell therapies, stem cell transplants, and other agents) were identified from the NCCN treatment guidelines. Approved indications were identified over the study period from the prescribing information of each available CAR T-cell therapy and the approval dates listed in FDA letters. Indications and treatments were mapped to the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) and Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS) codes.

Literature for claims-based algorithms was reviewed to identify eligible and treated patients and construct lines of therapy for the indications of interest. Cohorts and lines of therapy for each CAR T-cell therapy were identified in the CMS Medicare FFS Research Identifiable Files from 2015 to 2023. Patients were required to meet the following inclusion/exclusion criteria:

- One inpatient diagnosis code OR 2 outpatient diagnoses 30 to 365 days apart for an approved CAR T-cell therapy indication (the first diagnosis was the index diagnosis)
- Continuous enrollment in Medicare Parts A, B, and D for 365 days prior to the index diagnosis
- Aged 18+ years at index diagnosis
- No systemic therapies in 365 days prior to index diagnosis
- No diagnosis of remission or relapse prior to first systemic therapy
- For B-ALL, no diagnosis of T-cell leukemia or administration of bortezomib, daratumumab, or nelarabine

Patients receiving first-line systemic therapy were identified and followed for relapsed/refractory status until the end of FFS Medicare enrollment, death, or the end of data availability (i.e., December 31, 2023). Finally, patients eligible to receive CAR T-cell therapies based on approved indications at the time of treatment for relapsed/refractory disease and patients receiving CAR T-cell therapies were identified.

Limitations

The lines of therapy in the analysis were based on treatment changes and gaps and were used as a proxy for disease progression in the absence of detailed clinical information. This analysis utilized a 365-day window preceding the index diagnosis to identify systemic therapies. Patients may have been misclassified as initiating first-line therapy if they had been in remission for more than 1 year prior to the first observed diagnosis, resulting in an underestimation of uptake rates.

Additionally, this analysis identified 3,756 patients who received CAR T-cell therapy but did not meet the study inclusion/exclusion criteria. If excluded patients have different rates of CAR T-cell therapy eligibility or administration, uptake rates in this study would be biased. Eligibility for CAR T-cell therapy treatment was determined based on the patient's relapsed/refractory status without detailed medical records to determine clinical suitability for CAR T-cell therapy. Finally, this analysis does not account for proximity to CAR T-cell therapy treatment centers, availability of treatment, or other barriers to access.

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Magnolia market access