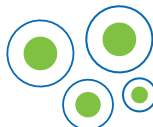


# CAR T-Cell Therapy 101: A Revolutionary Cancer Treatment

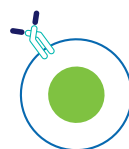
## What is CAR T and How Does it Work?

CAR (chimeric antigen receptor) T-cell therapy is a unique cancer treatment that genetically alters a patient's own cells to fight and kill cancerous ones. A personalized and revolutionary immunotherapy, CAR T is an essential tool for treating advanced forms of cancer and bringing new hope to patients and families.

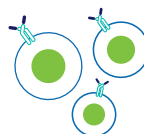
**1. T-Cell Collection:** A patient's T-cells, a type of white blood cell that fights infection, are collected from the patient's blood.



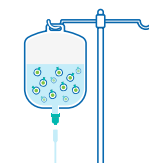
**2. Cell Re-Engineering & Manufacturing:** The T-cells are sent to a specialized manufacturing site where they are genetically engineered to produce new surface receptors, called chimeric antigen receptors (CARs), to target and kill cancer cells.



**3. Cell Proliferation:** The newly manufactured T-cells are multiplied and sent back to the hospital or center where the patient is being treated.



**4. Patient Treatment:** The CAR T-cells are returned to the patient's body, where they act as "living drugs" and have been shown in some cases to fight and kill cancer cells.<sup>1</sup>

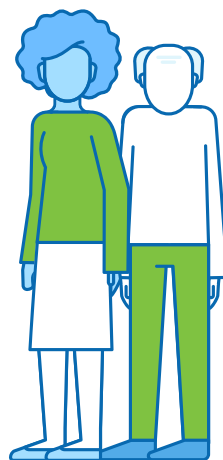


## Patient Eligibility

Four CAR T therapies have been approved by the FDA to treat patients with certain forms of leukemia and lymphoma, including:

- Adults with **relapsed or refractory mantle cell lymphoma**
- People under 25 with certain forms of **leukemia**
- Adults with certain forms of **B-cell lymphoma**
- Adults with certain forms of relapsed or refractory **large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) arising from indolent lymphoma**

Many patients who receive CAR T have exhausted all other treatment options or are participating in clinical trials.



## COVID-19's Impact on CAR T

**About half of American adults have said they or members of their households delayed medical care due to COVID-19**, including preventative cancer care screenings. Cancers caught later could be more extensive and have a bigger physical and mental strain on the patient and family.<sup>2</sup>



### 4 approved therapies

The FDA has approved four CAR T cell therapies for cancer treatment.<sup>3</sup>



### 630+ active trials

Many CAR T cell therapies are being evaluated in clinical trials for different types of cancer, including brain cancer, breast cancer, lung cancer, multiple myeloma and ovarian cancer.<sup>4</sup>

<sup>1</sup> Lim WA, June CH. The Principles of Engineering Immune Cells to Treat Cancer. *Cell*. 2017;168(4):724-740. doi:10.1016/j.cell.2017.01.016 Published February 2017. Accessed February 23, 2021.

<sup>2</sup> Hamel L, Kearney A, Kirzinger A, et al. Impact of Coronavirus on Personal Health, Economic and Food Security, and Medicaid, *Kaiser Family Foundation*. Published May 27, 2020. Accessed February 22, 2021. <https://www.kff.org/report-section/kff-health-track-ing-poll-may-2020-health-and-economic-impacts/>

<sup>3</sup> Approved Cellular and Gene Therapy Products. U.S. Food and Drug Administration website. Accessed February 17, 2021. <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>

<sup>4</sup> Clinical Trials Finder. *American Society of Gene and Cell Therapy* website. Accessed February 17, 2021. [Asgct.careboxhealth.com](https://www.asgct.org/careboxhealth.com)

# CAR T-Cell Therapy 101: A Revolutionary Cancer Treatment

## Promising Results

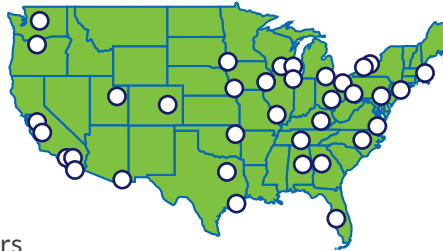
CAR T has generated impressive results for patient with blood cancer. In some studies, up to 90% of patients whose disease had either relapsed multiple times, or failed to respond to standard therapies, achieved remission after receiving CAR T-cell therapy.<sup>5</sup>

Clinical trials are ongoing for CAR T use in earlier lines of care. CAR T is also being studied in solid tumors and other blood cancers, with a multiple myeloma treatment expected in 2021.



## Access to CAR T

CAR Ts have shown to benefit patients and are cost-effective, but access is not necessarily guaranteed, especially among Medicare and Medicaid patients.<sup>6</sup>



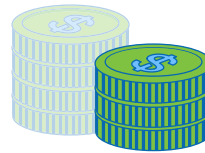
There are a limited number of specialized centers that meet the FDA's safety requirements to provide CAR T.<sup>7</sup> These geographic barriers are sometimes exacerbated by insurance coverage.

**Commercial Insurance:** Most commercial insurers cover CAR T therapies, but do so on an individual basis, creating single-patient agreements.

**Medicare:** Traditionally, Medicare has reimbursed hospitals at a lower rate than commercial insurers. Fortunately, in 2020 Medicare created a new hospital billing code. Championed by stakeholders, including patient advocacy groups, this development may increase access among Medicare patients.<sup>8</sup>



**Medicaid:** Most states do not have explicit Medicaid policies for reimbursing providers for administering CAR T. And in those states where Medicaid does have such policies, providers are still only partially reimbursed under them.<sup>9</sup>



CAR Ts are novel and complex. Treatments with these characteristics have been underutilized by historically disadvantaged groups, creating deepened health disparities in some cases.<sup>10</sup>



“The NCCN Guidelines for Patients let people know **CAR T-cell therapy is a powerful cell-based treatment capable of offering very durable responses** in difficult to treat blood cancers.”

**Brian Koffman**, MDCM (retired), MS Ed, Co-Founder, Executive VP and Chief Medical Officer CLL Society, Inc.



“CAR T therapy breaks a pattern of stagnant efficacy growth in pharmaceutical innovation and demonstrates significantly greater incremental effectiveness and similar cost-effectiveness to prior innovations.”

**CAR T therapy and historical trends in effectiveness and cost-effectiveness of oncology treatments**, *Journal of Comparative Effectiveness Research*

<sup>5</sup> CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY. *Leukemia & Lymphoma Society website*. Accessed February 23, 2021. <https://www.lls.org/treatment/types-of-treatment/immunotherapy/chimeric-antigen-receptor-car-t-cell-therapy>

<sup>6</sup> Koffman B. The Best Policy to Eliminate Barriers to Care. *Cure Today*. Published June 22, 2020. Accessed February 23, 2020. <https://www.curetoday.com/view/the-best-policy-to-eliminate-barriers-to-care>

<sup>7</sup> Medical Centers Offering CAR T-Cell Therapy. *BMTInfonet.org*. Accessed February 22, 2020. <https://www.bmtinfont.org/transplant-article/medical-centers-offering-car-t-cell-therapy>

<sup>8</sup> CMS Builds on Commitment to Transform Healthcare Through Competition and Innovation. Centers for Medicare and Medicaid Services website. Published May 11, 2020. Accessed February 22, 2020. <https://www.cms.gov/newsroom/press-releases/cms-builds-commitment-transform-healthcare-through-competition-and-innovation>

<sup>9</sup> Koffman B. The Best Policy to Eliminate Barriers to Care. *Cure Today*. Published June 22, 2020. Accessed February 23, 2020. <https://www.curetoday.com/view/the-best-policy-to-eliminate-barriers-to-care>

<sup>10</sup> Multiple Myeloma Draft Evidence Report. *Institute for Clinical and Economic Review*. Published February 11, 2021. Accessed February 22, 2021. <https://icer.org/assessment/multiple-myeloma-2021/#timeline>