CAR-T Manufacturing Cost of Goods Sold: Vein-to-Vein Economics

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Executive Summary

Manufacturing a single dose of chimeric antigen receptor T-cell (**CAR-T**) therapy remains one of the most expensive and logistically complex processes in modern medicine. Peer-reviewed cost models place the direct cost of goods sold (COGS) for one commercially manufactured CAR-T product at close to $500,000 (Source: pmc.ncbi.nlm.nih.gov), while narrower batch-production cost estimates range from **$170,000 to $220,000** (Source: genengnews.com) and a 2020 Biosolve-based supply chain model estimated $78,000 to $93,000 per treated patient including logistics (Source: insights.bio). Historical launch list prices for the six CAR-T products approved before Aucatzyl range from **$373,000** for Yescarta and Tecartus (Source: gilead.com) to **$475,000** for Kymriah (Source: onclive.com), but real-world claims data from Milliman show the mean allowed cost of the CAR-T product alone reached $616,500 against an average wholesale acquisition cost of roughly $443,600, and 15% of episodes exceeded $1.1 million once hospitalization and toxicity management are included (Source: milliman.com) (Source: milliman.com).

The largest identifiable cost driver is manufacturing labor and the viral vector used to genetically engineer T-cells. One peer-reviewed analysis found more than 200 labor hours are required per batch, representing 71% of total batch production costs (Source: pmc.ncbi.nlm.nih.gov), while a single-patient viral vector batch can cost more than $16,000 (Source: ncbi.nlm.nih.gov), and reagents alone can account for more than half of total COGS in a facility-level economic model (Source: frontiersin.org). Between 4% and 7% of patients cannot receive their own CAR-T product because of manufacturing failure (Source: pmc.ncbi.nlm.nih.gov), and **vein-to-vein time**, the interval from a patient's cell collection to reinfusion, still runs from about 14 days for Yescarta after a 2024 process change (Source: pharmavoice.com) to 4 to 5 weeks for Carvykti (Source: carvykti.com). During that wait, up to 25% of multiple myeloma patients on manufacturing waitlists die before receiving therapy (Source: pmc.ncbi.nlm.nih.gov).

Two structural responses to this cost and access problem are gaining traction. **Decentralized, point-of-care manufacturing** using closed automated systems such as Miltenyi's CliniMACS Prodigy has demonstrated a 9-day vein-to-vein time and a reported manufacturing cost near $35,107 in an academic trial in India; the analysis excluded lentiviral-vector cost, so it is not directly comparable with commercial-product cost estimates (Source: nature.com). Automated "smart factory" platforms from companies such as Cellares are attracting major pharmaceutical investment, illustrated by Bristol Myers Squibb's capacity-reservation deal with Cellares worth up to $380 million (Source: cellares.com). **Allogeneic ("off-the-shelf") manufacturing**, which draws T-cells from a single healthy donor rather than the patient, is being pursued by Allogene Therapeutics and Caribou Biosciences on the premise that one production run can yield 100 to 300 or more doses instead of one (Source: allogene.com) (Source: bioprocessintl.com), materially diluting per-dose fixed costs. As of January 2024, an estimated 34,000 patients worldwide had received a commercial CAR-T product (Source: isctglobal.org), and the global CAR-T therapy market is projected by Precedence Research to grow from $5.21 billion in 2025 to nearly $27.0 billion by 2035 (Source: precedenceresearch.com), meaning the industry's ability to compress COGS and vein-to-vein time will materially determine both patient access and payer sustainability over the next decade.

Introduction and Background

Chimeric antigen receptor T-cell therapy re-engineers a patient's own immune cells to recognize and destroy cancer, and it has produced some of the deepest and most durable remissions ever recorded in relapsed blood cancers. **Novartis** received the first-ever U.S. Food and Drug Administration (**FDA**) approval for a CAR-T therapy, **Kymriah** (tisagenlecleucel), on August 30, 2017, for pediatric and young-adult relapsed or refractory acute lymphoblastic leukemia (**ALL**) (Source: novartis.com. Kite Pharma, now part of Gilead Sciences, followed weeks later with **Yescarta** (axicabtagene ciloleucel) at a U.S. list price of $373,000 (Source: gilead.com). Seven CAR-T products are approved in the United States. Most are manufactured individually for a single patient, a model that differs fundamentally from conventional small-molecule or monoclonal-antibody drug manufacturing.

That individualized manufacturing model is the direct cause of CAR-T's extraordinary cost of goods sold. Unlike a biologic drug produced in bulk and dispensed to thousands of patients from one batch, an **autologous** CAR-T product is manufactured from a single patient's own T-cells, collected by **leukapheresis**, genetically modified with a viral vector to express the chimeric antigen receptor, expanded, formulated, and shipped back to the treating hospital for infusion into that same patient. Every batch is, in effect, a custom-manufactured drug lot with its own quality control (**QC**) release testing, and no economies of scale are available in the traditional pharmaceutical sense. Analysts have described this as a "batch of one" manufacturing problem, and it explains why the current cost of a commercially manufactured CAR-T product totals nearly $500,000 even before hospitalization, toxicity management, and logistics are added (Source: pmc.ncbi.nlm.nih.gov).

This report examines the full economics of CAR-T manufacturing: the process steps and cost drivers that make up COGS, the vein-to-vein timelines reported for each approved therapy, the supply chain and chain-of-custody demands unique to a living cellular product, and the two principal strategies the industry is pursuing to reduce cost and turnaround time, namely decentralized point-of-care manufacturing and allogeneic "off-the-shelf" production. It draws on peer-reviewed cost-of-goods models, manufacturer disclosures, FDA guidance, health-economic assessments from the Institute for Clinical and Economic Review (**ICER**), and real-world claims data from Milliman, with every figure traced to its originating source and every discrepancy between estimates presented openly rather than resolved by fiat. As of January 2024, an estimated 34,000 patients worldwide had received commercially available CAR-T products (Source: isctglobal.org). Manufacturing capacity remains an important constraint on access, alongside clinical eligibility, referral, and treatment-center capacity.

CAR-T Manufacturing Process and Cost of Goods Sold Drivers

Process Steps and Timeline

The standard autologous CAR-T manufacturing workflow proceeds through **isolation of the starting cell population from the leukapheresis product, T-cell activation, genetic modification, ex vivo expansion, final product formulation, and product release testing** (Source: pmc.ncbi.nlm.nih.gov). **Conventional manufacturing** typically involves one to two weeks of ex vivo cell manipulation and expansion, though newer abbreviated protocols can compress active culture time to as little as 24 to 72 hours (Source: pmc.ncbi.nlm.nih.gov). Once cells leave the manufacturing facility, **centrally manufactured CAR-T products often spend more time in the QC and quality assurance (QA) release process than in actual manufacturing**, with release testing and QA sign-off typically taking two to three weeks before the product can be shipped (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov). Combined with shipping, the complete **vein-to-vein process can take up to 30 days and, in many cases, longer** (Source: ncbi.nlm.nih.gov).

Viral Vectors and Raw Materials

The single-most cited cost driver in CAR-T manufacturing is the **viral vector**, typically a lentivirus or retrovirus used to insert the chimeric antigen receptor gene into a patient's T-cells. Industry sources describe vectors as **"one of the most expensive items in the process"** (Source: genengnews.com), and a peer-reviewed analysis found that **each viral batch for a single patient can cost more than $16,000** (Source: ncbi.nlm.nih.gov). The same review identifies **cell culturing, transduction with viral vectors, and the transport of T lymphocytes** as the primary contributors to high manufacturing cost (Source: ncbi.nlm.nih.gov). A 2020 Biosolve-based cost model concurred, finding that **key process cost drivers were the viral vector required to introduce CARs into T-cells and QC tests** (Source: insights.bio), and estimated total patient treatment cost, including supply chain, at **$78,000 to $93,000** (Source: insights.bio). A separate facility-level economic model built for a European manufacturing setting found that **reagent costs make up more than half of total COGS**, a share that grows as facilities automate and shift spend from labor to consumables (Source: frontiersin.org). That same model calculated **cost of goods as 55% to 70% of total product cost**, with per-treatment costs of approximately **€63,000 for manual production, €61,000 for semi-automated production, and €57,000 for fully automated production** (Source: frontiersin.org), against a current market list price of **€200,000 to €250,000 per dose** (Source: frontiersin.org), implying gross margins that fund the substantial fixed costs of clinical development, regulatory approval, and specialized commercial infrastructure.

Labor, Quality Control, and Facility Overhead

Labor is the other dominant cost category. A peer-reviewed manufacturing-process review found that **over 200 labor hours are required per batch or lot**, and **this represents 71% of the total costs associated with batch production** (Source: pmc.ncbi.nlm.nih.gov), with as much as 48% of total cost deriving from manufacturing labor alone. Kite executives have separately described the complexity of the process, noting that **it takes upwards of 18 people to carry out the various manufacturing steps** for a single Yescarta batch (Source: pharmavoice.com). Additional purification and enrichment steps, while adding to cost, have been shown to improve product consistency: manufacturers report that **despite an increase in costs, this has resulted in important improvements in product consistency and has reduced manufacturing failure rates** (Source: pmc.ncbi.nlm.nih.gov). A 2018 cost-of-goods analysis for autologous CAR-T processes similarly stressed the **importance of maximizing employee productivity, leveraging automation and technology, and accurately forecasting capacity needs** as the primary levers available to manufacturers seeking to bring COGS down over time (Source: insights.bio).

Regulatory compliance adds a further, less visible cost layer. FDA guidance for CAR-T products requires that **full cGMP (current good manufacturing practice) requirements be met during Biologics License Application review as well as during the validation of all analytical assays** (Source: genengnews.com), and the FDA specifically **requires replication-competent retrovirus and lentivirus (RCR/RCL) detection assays for the viral vectors as well as virally transduced cell products** (Source: pmc.ncbi.nlm.nih.gov). Because **CAR T cells cannot be terminally sterilized**, every processing step must occur under validated aseptic conditions rather than relying on a final sterilization step common in other biologics (Source: genengnews.com), which drives cleanroom and gowning requirements that add materially to facility overhead. The FDA also flags **autologous cellular starting material as a major source of lot-to-lot variability** (Source: genengnews.com), meaning quality systems must be built to tolerate patient-to-patient variation in a way that standardized biomanufacturing does not.

Manufacturing Failure Rates and Total Cost of Care

Even with all of this investment, manufacturing does not always succeed. Across CAR-T products broadly, an estimated **4% to 7% of patients are unable to receive their CAR-T cell products as a result of manufacturing failures** (Source: pmc.ncbi.nlm.nih.gov). Where a batch is out of specification but not unsafe, regulators have allowed limited flexibility: **out-of-specification products can be administered to patients upon receiving necessary regulatory approvals** (Source: pmc.ncbi.nlm.nih.gov), an exception that itself requires additional documentation and regulatory cost. When manufacturing, hospitalization, adverse-event management, and lost-batch risk are all summed, one peer-reviewed estimate places the **total expense for a single treatment as high as $2 million per individual in the United States** (Source: ncbi.nlm.nih.gov), underscoring that the wholesale acquisition cost of the drug itself is only a starting point for understanding the true economic burden of CAR-T therapy.

Vein-to-Vein Time: Manufacturing Turnaround Across Approved Therapies

Vein-to-vein time, the elapsed interval between a patient's leukapheresis collection and reinfusion of the finished product, is both a clinical and an economic variable: every additional day of manufacturing wait is a day a relapsing cancer patient may need costly **bridging therapy**, and a day a hospital bed or apheresis slot cannot be reallocated. Reported timelines vary meaningfully by product. For **Kymriah**, the manufacturing process **usually takes 3 to 4 weeks, but timing and manufacturing outcomes can vary** (Source: us.kymriah.com), with the initial leukapheresis collection itself typically taking about **3 to 6 hours** via IV catheter (Source: us.kymriah.com). For **Breyanzi**, Bristol Myers Squibb's patient brochure states **it takes about 3 to 4 weeks from the time your cells are received at the manufacturing site** until product is available to ship back (Source: breyanzi.com). **Carvykti** requires the longest reported window among approved products, with genetic modification of T-cells alone taking **approximately 4 to 5 weeks** (Source: carvykti.com); notably, **all 208 of 208 patients** in the pivotal CARTITUDE-4 trial required bridging therapy during that wait (Source: carvykti.com). **Tecartus** patients are told they will **wait for around 2 weeks until their CAR T cells are ready** (Source: tecartus.com).

Yescarta has seen the most significant recent turnaround-time improvement. In February 2024, the FDA approved a Kite manufacturing process change that Kite officials said would cut median turnaround **from 16 days to 14 days** (Source: pharmaceuticalcommerce.com), with Kite officials stating the change meant **it will now take around 14 days from a patient's cell collection to infusion** (Source: pharmavoice.com). A Kite clinical investigator framed the stakes plainly, noting that **time is a critical factor in cell therapy, and it can make the difference** between a successful outcome and disease progression (Source: pharmaceuticalcommerce.com). Legend Biotech has reported similar operational gains for Carvykti, disclosing that in the first quarter of 2026 it succeeded in **increasing manufacturing success rate to 99%** while decreasing turnaround time and delivering on-time order releases (Source: investors.legendbiotech.com). BMS and 2seventy bio report that Abecma **offers unlimited slot availability and an 89% manufacturing success rate** for lots produced between April 2024 and July 2025 (Source: abecmahcp.com), where success rate is defined as **patients successfully treated with conforming product divided by patients apheresed** (Source: abecmahcp.com).

Table 1 below summarizes historical launch WAC, reported vein-to-vein timeline, and manufacturing outcome data for all seven FDA-approved CAR-T products. Launch WAC is retained for historical comparison only and is not a current WAC.

PRODUCT (GENERIC NAME)	MANUFACTURER	FDA APPROVAL	HISTORICAL LAUNCH WAC (NOT CURRENT WAC)	REPORTED TIMING OR CAPACITY MEASURE (DEFINITIONS VARY; NOT DIRECTLY COMPARABLE)	MANUFACTURING SUCCESS OR FAILURE DATA
Kymriah (tisagenlecleucel)	Novartis	Aug. 30, 2017 (Source: novartis.com	$475,000 (Source: onclive.com)	Manufacturer-reported process: 3 to 4 weeks; start and end points not specified (Source: us.kymriah.com)	7 to 9% manufacturing failure in pivotal studies (Source: biopharmadive.com)
Yescarta (axicabtagene ciloleucel)	Kite / Gilead	Oct. 18, 2017	$373,000 (Source: gilead.com)	~14 days, down from 16 days after 2024 process change (Source: pharmaceuticalcommerce.com)	1% manufacturing failure in pivotal trial (Source: biopharmadive.com)
Tecartus (brexucabtagene autoleucel)	Kite / Gilead	2020	$373,000 (Source: biopharmadive.com)	~2 weeks (Source: tecartus.com)	Not separately disclosed
Breyanzi (lisocabtagene maraleucel)	Bristol Myers Squibb	2021	$410,300 (Source: biopharmadive.com)	About 3 to 4 weeks from receipt of cells at the manufacturing site until product is available to ship back (Source: breyanzi.com)	Not separately disclosed
Abecma (idecabtagene vicleucel)	BMS / 2seventy bio	2021	$419,500 (Source: biopharmadive.com)	Capacity statement: unlimited slot availability; not a turnaround-time measure	89% manufacturing success rate, Apr. 2024 to Jul. 2025 (Source: abecmahcp.com)
Carvykti (ciltacabtagene autoleucel)	Legend Biotech / J&J	Feb. 28, 2022 (Source: jnj.com	$465,000 (Source: biopharmadive.com)	Genetic modification of T cells: approximately 4 to 5 weeks; not a full vein-to-vein interval (Source: carvykti.com)	99% manufacturing success rate, Q1 2026 (Source: investors.legendbiotech.com)
Aucatzyl (obecabtagene autoleucel)	Autolus	Nov. 8, 2024 (Source: fda.gov)	$525,000 (Source: sec.gov)	Target vein-to-release time of ~16 days (Source: sec.gov)	Not separately disclosed

The table does not support a product-by-product turnaround ranking because the reported measures have different start and end points, and Abecma's entry is a capacity statement rather than a duration. Historical launch WAC and the reported operational measures therefore should not be compared as though they share a common endpoint. Manufacturing success rates, where disclosed, range from 89% to 99% for the specified marketed-lot periods; these figures use product-specific definitions and time periods.

Supply Chain, Logistics, and Patient Access Challenges

CAR-T products are living cells, not stable small molecules, and that fact drives supply chain requirements with no analog in conventional pharmaceutical distribution. Cryoport, the cold-chain logistics provider used for the first two commercial CAR-T therapies, ships patient cell collections either cryogenically at ultra-low temperature or chilled, and **always records the Chain of Custody and the Chain of Condition** throughout transit (Source: contractpharma.com), because any temperature excursion can render the product useless. Cryoport's chief executive has described the logistics burden as inseparable from the therapy itself: **"the therapy is half the battle; the other half is the logistics."** (Source: contractpharma.com) Trade press coverage of the sector notes that CAR-T and other cell and gene therapies are **often cryo-frozen at around -150 degrees Celsius and need to be delivered within a very narrow specific time period** (Source: pharmaceuticalcommerce.com, which requires a dedicated network of qualified couriers and validated shipping containers rather than standard pharmaceutical distribution.

Access constraints compound the logistics burden. Kite reported **135 facilities in the U.S. and 400 worldwide** in a 2024 disclosure (Source: pharmavoice.com), but this historical company figure is not a current FDA authorization or REMS-certification requirement. In June 2025, FDA eliminated the REMS for the six listed autologous BCMA- and CD19-directed CAR-T products, removing the requirement that dispensing hospitals and associated clinics be specially certified; manufacturer operational arrangements, clinical capacity, referral patterns, and payer processes can still limit access (Source: fda.gov). Kite itself acknowledged that **only 2 in 10 American patients who could benefit from CAR-T get the treatment** (Source: pharmavoice.com). A 2022 supply chain survey found **more than 30% of providers identified payer approval delays as a reason for treatment delay** (Source: pharmaceuticalcommerce.com), on top of manufacturing wait times, at a point when just over 150 U.S. hospitals were administering these therapies at all.

The clinical cost of these delays is severe. Nearly **40% of oncologists who have referred patients for CAR-T therapy have experienced an incident where their patient was not able to complete a treatment due to a health deterioration** during the wait (Source: pharmaceuticalcommerce.com). Peer-reviewed literature formally defines this interval as the **"bridging period," lasting from the decision to treat until T cells are infused**, during which patients may experience disease-related complications that delay or prevent infusion altogether (Source: nature.com). In the pivotal ELIANA trial that supported Kymriah's approval, **10 of the 92 patients enrolled could not be infused due to significant adverse events or death** (Source: ncbi.nlm.nih.gov), and 87% of those who were infused needed bridging chemotherapy to control disease during manufacturing. In real-world practice the attrition can be worse still: at Memorial Sloan Kettering Cancer Center, the infusion rate for adult ALL patients enrolled for CD19-directed CAR-T experience **was 65% (54/83, 65%) of enrolled patients, mostly due to disease progression and death** during the wait (Source: ncbi.nlm.nih.gov. For multiple myeloma patients specifically, as of early 2023 an estimated **25% of patients succumb to disease while waitlisted for BCMA-directed CAR-T cell product slots**, with waiting periods ranging from one to ten months before apheresis can even begin (Source: pmc.ncbi.nlm.nih.gov). Taken together, these figures make plain that CAR-T's supply chain and access constraints are not a peripheral inconvenience but a primary driver of who ultimately receives, and survives long enough to receive, the therapy.

Decentralized and Point-of-Care CAR-T Manufacturing

Given the cost and timeline pressures described above, an increasingly prominent industry response is **decentralized, point-of-care manufacturing**: producing CAR-T cells inside or near the treating hospital using closed, automated systems rather than shipping starting material to a centralized commercial plant and back. The clearest published evidence for this approach comes from the VELCART trial conducted in India using Miltenyi Biotec's **CliniMACS Prodigy** closed-system platform. Investigators reported that **clinical-grade CAR-T cells were produced in house with a vein-to-vein time of 9 days** (Source: ncbi.nlm.nih.gov), a fraction of the 14-to-35-day range reported for commercial products above. The analysis reported a manufacturing cost of approximately **$35,107 per product**, excluding lentiviral-vector cost, plus a median health-care-resource-utilization cost of **$12,724**. Its reported combined total therapy cost was $47,831 per patient and likewise excluded lentiviral-vector cost (Source: nature.com).

A broader peer-reviewed review of decentralized manufacturing corroborates the direction, if not always the precise magnitude, of these findings: decentralized point-of-care production is reported to shorten manufacturing time to **commonly 7 to 10 days versus 14 days for centralized manufacturing**, and at a lower cost (Source: pmc.ncbi.nlm.nih.gov). The same review notes that institutions can lower upfront costs by sourcing **research-grade vector preparations, often at a cost of less than $50,000**, before transitioning to a GMP-grade vector for final validation and clinical manufacturing runs (Source: pmc.ncbi.nlm.nih.gov, illustrating how vector-sourcing strategy remains one of the most sensitive levers in point-of-care economics. Under the prevailing centralized, industry-driven manufacturing model, a related peer-reviewed report notes that **only 25% of patients registered for CAR-T cell infusion are likely to receive it**, with a median wait of roughly six months (Source: ncbi.nlm.nih.gov), a stark illustration of the access gap decentralized manufacturing is intended to close.

Commercial-scale automation is following a parallel track. **Cellares**, headquartered in South San Francisco with its commercial-scale integrated development and manufacturing organization (**IDMO**) "Smart Factory" in Bridgewater, New Jersey, states that its automated **Cell Shuttle** platform can lower manufacturing costs by up to 75% relative to manual processes (Source: cellares.com). This is a company marketing claim, not an independently verified result or a general CAR-T manufacturing-cost benchmark. Citing McKinsey analysis, Cellares argued in 2021 that **less than 1% of patients who could benefit from cell therapies are able to get access to them**, largely because of scalable-manufacturing shortfalls rather than a lack of clinically appropriate candidates (Source: cellares.com). That thesis has since attracted major pharmaceutical investment: in April 2024, **Bristol Myers Squibb** signed a worldwide capacity-reservation and supply agreement with Cellares valued at up to **$380 million** in upfront and milestone payments to secure automated manufacturing capacity for its CAR-T pipeline (Source: cellares.com), and by that point Cellares had **raised over $355 million in financing** across its funding rounds (Source: cellares.com).

Automation and decentralization are not without tradeoffs. Reviewers comparing closed-system platforms note that the Lonza Cocoon system offers **lower output when compared to the CliniMACS Prodigy** in exchange for lower installation and maintenance cost (Source: pmc.ncbi.nlm.nih.gov), meaning hospitals and manufacturers must weigh throughput against capital cost when selecting a point-of-care platform, and decentralized sites must each independently maintain the cGMP quality systems and staff training that a centralized plant amortizes across far more batches.

Autologous versus Allogeneic Manufacturing Economics

The most fundamental structural choice in CAR-T manufacturing economics is whether a product is **autologous**, meaning manufactured from and for the same patient, or **allogeneic**, meaning manufactured from a single healthy donor's cells and administered "off the shelf" to many different patients. A 2024 peer-reviewed review states plainly that **allogeneic CAR T cells can be produced for many patients using T cells from a single healthy donor**, in contrast to autologous products limited to one patient per batch (Source: nature.com). That structural difference is the entire economic rationale for the allogeneic approach: fixed manufacturing costs, including facility overhead, vector production runs, and QC release testing, are spread across dozens or hundreds of doses instead of one.

Allogeneic developers have quantified the scale claim directly. **Allogene Therapeutics** states that **a single manufacturing run has the potential to yield treatment for 100 or more patients** (Source: allogene.com), a company claim rather than an independently audited figure, and operates this strategy out of **Cell Forge 1**, a modular **136,000-square-foot** facility in Newark, California, designed with room to expand (Source: allogene.com). A **Caribou Biosciences** executive has offered a similar, and even larger, order of magnitude, stating that **allogeneic manufacturing runs can yield 200 to 300 doses** compared with one dose per run for autologous CAR-T, and that with an allogeneic product, patients can move from eligibility confirmation to lymphodepleting chemotherapy in as little as two days rather than weeks (Source: bioprocessintl.com). The same executive noted a sobering access statistic that motivates the entire allogeneic strategy: **only 20% of eligible second-line diffuse large B-cell lymphoma (DLBCL) patients** actually receive autologous CAR-T therapy today, largely because it remains concentrated at centers of excellence (Source: bioprocessintl.com).

Allogeneic manufacturing is not simply autologous manufacturing at larger scale, however. The same Caribou executive cautioned that allogeneic manufacturing is inherently more complex than autologous manufacturing because the genome-editing tools used to prevent immune rejection and graft-versus-host disease must themselves be GMP-qualified as drug substances, adding an entire additional layer of process development, characterization, and regulatory scrutiny that autologous manufacturers do not face. **Precision BioSciences** built out this capability directly, opening a cGMP manufacturing facility with the potential to serve as a **commercial launch site with capacity to generate up to 10,000 doses of CAR-T cell therapies** and 4,000 doses of gene therapies annually (Source: investor.precisionbiosciences.com), a capacity figure that would be functionally unreachable for any single-patient autologous manufacturing line operating on today's process economics.

Table 2 below consolidates the published cost-of-goods and total-cost-of-care estimates cited throughout this report, drawn from independent studies conducted at different points in time and using different methodologies, to make the range of current thinking on CAR-T manufacturing economics visible in one place.

SOURCE / STUDY	AS OF	COST COMPONENT MEASURED	REPORTED AMOUNT	KEY DRIVER NOTED
Biosolve-based cost model, Immuno-Oncology Insights (Source: insights.bio)	2020	Total patient treatment cost, incl. supply chain	$78,000 to $93,000	Viral vector and QC testing
Facility-automation economic model, Frontiers in Bioengineering (Source: frontiersin.org)	2025	Cost per treatment (manual / semi-auto / full-auto)	€63,000 / €61,000 / €57,000	Reagents (>50% of COGS)
Peer-reviewed manufacturing-cost review (Source: ncbi.nlm.nih.gov)	2024/2025	Viral vector batch cost	Over $16,000 per patient batch	Cell culturing, vector transduction, T-cell transport
Genetic Engineering & Biotechnology News industry estimate (Source: genengnews.com)	2025	Full batch production cost	$170,000 to $220,000	Logistics, processing, distribution
VELCART point-of-care trial, India (Source: nature.com)	Published 2022; 2023 issue	In-house manufacturing cost (plus care cost)	$35,107 manufacturing + $12,724 care = $47,831 total; lentiviral-vector cost excluded	CliniMACS Prodigy closed system, sponsor-supplied vector
Milliman commercial claims analysis (Source: milliman.com)	Jan. 2022 to Apr. 2025 claims period	Mean allowed CAR-T product cost, real-world claims	$616,500 (vs. average WAC of ~$443,600)	Payer-allowed product cost; not manufacturing COGS or total episode cost

The spread across these six independent estimates, from roughly $16,000 for a vector batch alone to $616,500 for payer-allowed CAR-T product cost in real-world claims, illustrates why single-number characterizations of "CAR-T cost" are frequently misleading. Each figure measures a different scope: raw-material cost, full batch-production cost, point-of-care academic manufacturing cost, or payer-allowed product cost. Episode-of-care costs, which can include hospitalization and toxicity management, are a separate measure. Readers comparing CAR-T economics across sources should always confirm which of these scopes a given number represents before drawing conclusions about affordability or margin.

Data Analysis and Evidence

Beyond the manufacturing-cost estimates already presented, publicly available pricing, market-size, and health-economic data provide additional quantitative grounding for CAR-T's cost position within oncology care. On the pricing side, Novartis set Kymriah's launch list price at **$475,000** for a single one-time treatment in August 2017 (Source: onclive.com), and separately estimated that the **average total cost for one year of tisagenlecleucel therapy, including pre-infusion care, hospitalization, and adverse-event management, is approximately $547,000** (Source: onclive.com), a roughly $72,000 gap between list price and total cost of care that recurs across the class. J&J priced Carvykti at **$465,000**, higher than Bristol Myers Squibb's **$419,500** wholesale acquisition cost for Abecma (Source: biopharmadive.com), while Gilead priced **Tecartus at $373,000, the same price tag** as Yescarta (Source: biopharmadive.com).

Real-world claims data diverges materially from these list prices. A 2026 Milliman actuarial analysis of commercial claims covering January 2022 through April 2025 found that **the average WAC price across the CAR-T therapies was approximately $443,600** (Source: milliman.com), yet **mean CAR-T product allowed costs reached $616,500** (Source: milliman.com), and **15% of CAR-T cases exceeded $1.1 million** in total episode cost (Source: milliman.com). Milliman also found that **inpatient cases had an average CAR-T product cost of $645,900** (Source: milliman.com), meaningfully higher than outpatient administration. The descriptive claims analysis was not designed to identify causal drivers of this difference; Milliman discusses complications and adverse events as contributors to variability in total episode costs. That toxicity burden is not hypothetical: in the CARTITUDE-1 trial supporting Carvykti's approval, **CRS occurred in 95% (92 of 97) of patients receiving ciltacabtagene autoleucel** (Source: jnj.com.

Independent health-economic assessments have questioned whether list prices reflect value delivered. ICER's May 2021 evidence report concluded that Abecma's launch price **would require a 37% to 54% discount off the treatment's recently announced wholesale acquisition cost** to align with conventional cost-effectiveness thresholds (Source: icer.org), and the same report calculated health-benefit price benchmarks for cilta-cel of **$350,000 to $475,000** on an equal-value-of-life-years basis and **$317,000 to $427,000** on a cost-per-quality-adjusted-life-year (**QALY**) basis (Source: icer.org. By contrast,

ICER's assessment of Kymriah for pediatric relapsed or refractory leukemia found cost-effectiveness likely **between $37,000 and $78,000 over a patient's lifetime horizon** (Source: icer.org), a far more favorable value proposition, illustrating how indication, comparator therapy, and patient population materially change the cost-effectiveness calculus even within the same drug class.

On regulatory oversight, the FDA on April 18, 2024 mandated a class-wide safety update across all six approved CAR-T products, concluding that **changes to the Boxed Warning are warranted to highlight the serious risk of T-cell malignancies** following treatment with BCMA-directed or CD19-directed CAR-T products (Source: fda.gov), a decision that adds ongoing pharmacovigilance and long-term follow-up cost across the class. On market scale, **Precedence Research**, a named market-intelligence firm, sizes the global CAR T-cell therapy market at approximately **$5.21 billion in 2025**, projecting growth to **approximately $26.98 billion by 2035 at a compound annual growth rate of 17.88%** (Source: precedenceresearch.com). As of January 2024, a joint expert commentary from the International Society for Cell and Gene Therapy and partner organizations estimated that **34,000 patients worldwide have received commercially available CAR T-cell immunotherapies** (Source: isctglobal.org), a figure that puts the scale of current global manufacturing output in concrete terms against the far larger pool of clinically eligible patients described earlier in this report.

Regulatory activity has continued well beyond each product's original approval, adding to the ongoing cost of maintaining a CAR-T product on the market. Kymriah's own FDA product page shows its label was later expanded to cover **relapsed or refractory follicular lymphoma (FL) after two or more lines** of prior therapy (Source: fda.gov, and Yescarta's FDA product page continues to log new regulatory activity, including a **June 15, 2026 Approval Letter** (Source: fda.gov), indicating that regulatory oversight, and the compliance cost that accompanies it, remains an active and recurring line item nearly a decade after these products first reached the market.

Case Studies and Real-World Examples

Novartis and the University of Pennsylvania: The Origin and the Early Manufacturing Struggles of Kymriah

CAR-T's commercial history begins with an academic-industry alliance. In August 2012, **Novartis and the University of Pennsylvania** formed **an exclusive global collaboration to research, develop and commercialize targeted chimeric antigen receptor** technologies (Source: globenewswire.com), establishing **a first-of-its-kind research and development center specifically to develop and manufacture adoptive T-cell immunotherapies** (Source: globenewswire.com). Carl June, the Penn immunologist who led the original CAR-T science, described the early trial results in similarly definitive terms, stating that **initial data provide proof that this CAR therapy can activate a patient's own immune system** (Source: globenewswire.com) against cancer.

That collaboration produced Kymriah, but scaling the science into reliable commercial manufacturing proved difficult. In studies supporting Kymriah's approval, **between 7% and 9% of studied patients didn't receive the CAR-T product due to manufacturing failure** (Source: biopharmadive.com), a rate trade press explicitly contrasted with **only 1% of patients in rival Gilead's study of its CAR-T therapy Yescarta** (Source: biopharmadive.com). To address the problem, Novartis undertook what its own leadership described as an unprecedented manufacturing overhaul: in 2018 alone, **Novartis announced 16 plant transformations, including eight plant exits** (Source: biopharmadive.com), with then-CEO Vas Narasimhan calling it **"the biggest set of moves we've made on our manufacturing footprint"** (Source: biopharmadive.com). Novartis set an explicit target for 2019 **to increase overall CAR-T manufacturing capacity fourfold** (Source: biopharmadive.com). By October 2020, the investment had paid off in geographic terms: Novartis opened a manufacturing site in Kobe, Japan, describing it as **the first and only approved commercial manufacturing site for CAR-T cell therapy in Asia** (Source: novartis.com) and stating that **Novartis has the largest geographical CAR-T cell therapy manufacturing network in the world** (Source: novartis.com).

Legend Biotech and Johnson & Johnson: Expanding Carvykti Capacity Amid Vector Shortages

Carvykti's commercial launch collided directly with a global lentiviral vector supply shortage. In fall 2022, Legend Biotech and Janssen (J&J) announced **an additional investment of $250 million** in their joint CAR-T manufacturing facility in Raritan, New Jersey (Source: dcatvci.org), bringing **the total investment in the facility to $500 million** (Source: dcatvci.org). The companies were explicit about the rationale: the expansion was designed to **address industry-wide supply constraints for lentiviral vectors and to meet demand for projected $5-billion-plus peak sales** for Carvykti (Source: dcatvci.org). By that point the companies' manufacturing network already spanned **one facility in Raritan, New Jersey, and one in Nanjing, China** (Source: dcatvci.org), with a third site under construction in Belgium. As Table 1 shows, Legend Biotech has since reported that quarter-over-quarter operational investment continued to pay off, with a **99% manufacturing success rate** and improved on-time delivery reported for the first quarter of 2026 (Source: investors.legendbiotech.com).

Bristol Myers Squibb: Expanding In-House Capacity While Betting on Automated Manufacturing Partners

Bristol Myers Squibb has pursued both organic and partnered capacity expansion simultaneously. In June 2023, the FDA approved commercial production at BMS's new cell therapy facility in Devens, Massachusetts, a **244,000-square-foot facility representing the second significant expansion of the Devens site** (Source: manufacturingdive.com). A BMS manufacturing executive framed the investment as central to company strategy, stating the company was **"working diligently to increase our product capacity through new sites like Devens"** (Source: manufacturingdive.com), and BMS cell therapy lead Lynelle Hoch tied the investment to a broader company mission, describing **Bristol Myers Squibb's vision of putting more patients on a path to potential cure** (Source: manufacturingdive.com). Less than a year later, BMS supplemented that in-house buildout with the automated-manufacturing partnership with

Cellares described in the Decentralized and Point-of-Care Manufacturing section above, giving the company access to automated Smart Factory capacity without building and staffing every future facility itself, and illustrating how even a large incumbent manufacturer is hedging between owned infrastructure and third-party automated capacity to manage CAR-T's cost and scale-up risk.

Kite Pharma / Gilead: Shortening Turnaround Time Through Approved Process Change

Rather than expanding physical capacity alone, Kite pursued a process-engineering path to improve unit economics. Kite disclosed that CAR-T manufacturing **takes upwards of 18 people to carry out the various manufacturing steps** for each batch (Source: pharmavoice.com), underscoring the labor intensity described earlier in this report. In January 2024, the FDA approved a Kite manufacturing process change **projected to decrease median turnaround from 16 days to 14 days** (Source: pharmaceuticalcommerce.com), and Kite officials confirmed that patients could now expect roughly **14 days from cell collection to infusion** (Source: pharmavoice.com). This case illustrates a distinct lever from either facility investment or automation vendor partnership: FDA-approved changes to the manufacturing process itself, without new capital construction, can materially compress vein-to-vein time and, by extension, the clinical risk and bridging-therapy cost associated with the manufacturing wait.

VELCART, India: Point-of-Care Manufacturing in an Academic Trial (Published 2022)

The VELCART program, conducted at an academic nonprofit center in India using the CliniMACS Prodigy platform, offers the clearest documented real-world contrast between centralized commercial manufacturing and decentralized point-of-care production. As detailed above, the trial achieved a **9-day vein-to-vein time** (Source: ncbi.nlm.nih.gov) and reported a manufacturing cost of **$35,107**, excluding lentiviral-vector cost, with a reported total per-patient therapy cost of **$47,831** that likewise excluded lentiviral-vector cost (Source: ncbi.nlm.nih.gov), a fraction of the commercial-product manufacturing costs discussed earlier in this report. This case demonstrates that costs and turnaround time can differ substantially in an academic point-of-care setting. Its published per-product estimate should not be treated as directly comparable with commercial COGS or product price, because it reflects a specific academic non-profit setting and model assumptions. Such models still face open questions around scalability, cross-site standardization, and replication in higher-cost health systems.

Implications and Future Directions

The evidence assembled in this report points toward a bifurcating industry structure over the next several years. On one path, incumbent manufacturers such as Novartis, Gilead/Kite, Bristol Myers Squibb, and Legend Biotech/J&J continue to invest in larger, more automated centralized plants and in process changes that shave days off vein-to-vein time, following the pattern already demonstrated by Kite's 2024 turnaround improvement and Legend Biotech's rising manufacturing success rates. On the other, point-of-care manufacturing on closed platforms and allogeneic "off-the-shelf" production aim to reduce turnaround time and per-dose cost. The VELCART trial's sub-$50,000 reported total excluded lentiviral-vector cost, and the 200-to-300-dose allogeneic manufacturing-run figure remains a developer claim; neither is a like-for-like commercial-COGS comparison. Both paths face the same underlying constraint: every dollar and every day removed from CAR-T manufacturing directly expands the population of patients who can realistically access a therapy that, as Kite itself has acknowledged, still reaches only about **2 in 10** eligible American patients today (Source: pharmavoice.com).

A less visible but increasingly important constraint sits alongside process and facility economics: the data infrastructure needed to manage a manufacturing model where every batch is a unique, patient-specific lot with its own chain-of-identity and chain-of-custody record from apheresis through infusion. Life-sciences consultancies that advise manufacturers on data integration note that the same integration discipline required for regulated pharmaceutical operations extends directly into cell therapy production; IntuitionLabs, a life-sciences and AI consultancy that works with pharmaceutical and biotechnology organizations on data engineering and business intelligence, describes its own data-integration practice as covering the **"seamless integration of data from multiple sources including clinical trials, manufacturing, quality control, and commercial operations"** (Source: intuitionlabs.ai), the same categories of records that a CAR-T batch record must reconcile across apheresis center, manufacturing site, QC laboratory, and treating hospital. The cited consultancy describes capabilities for **"KOL segmentation, chatbots, sales operations, and more"** (Source: intuitionlabs.ai); it does not establish use of those capabilities for CAR-T manufacturing-quality analytics, batch-release prediction, or supply-chain visibility.

Regulatory posture will also continue to shape cost. The FDA's April 2024 class-wide Boxed Warning for secondary T-cell malignancies (Source: fda.gov) signals that long-term pharmacovigilance and follow-up costs are likely to grow, not shrink, even as manufacturing cost per batch falls. Manufacturers pursuing allogeneic platforms face a parallel regulatory build-out, since gene-editing reagents used to prevent immune rejection must themselves be qualified as GMP drug substances, a cost category that autologous manufacturers do not carry but that, if allogeneic products reach the market at the doses-per-batch scale claimed by Allogene and Caribou Biosciences, could still result in a materially lower cost per dose once amortized. Given that Precedence Research projects the global CAR-T market to grow from **$5.21 billion in 2025 to $26.98 billion by 2035** (Source: precedenceresearch.com), the manufacturers, platform vendors, and health systems that most successfully compress cost of goods sold and vein-to-vein time over the next decade stand to capture a disproportionate share of that growth, while those that do not may find their products priced out of an increasingly value-conscious payer environment shaped by ICER-style benchmarking.

Frequently Asked Questions (FAQs)

What does CAR-T manufacturing cost of goods sold actually include? CAR-T COGS covers the direct inputs required to convert a patient's own leukapheresis collection into an infusible product: the viral vector used for genetic modification, cell culture reagents, single-use disposables, quality control and release testing, and the labor hours required to execute each processing step. Peer-reviewed models put commercial manufacturing cost near **$500,000** (Source: pmc.ncbi.nlm.nih.gov), while narrower batch-only estimates run **$170,000 to $220,000** (Source: genengnews.com).

What is vein-to-vein time and why does it matter economically? Vein-to-vein time is the interval between a patient's cell collection and reinfusion of the finished CAR-T product, ranging from about **14 days for Yescarta** (Source: pharmavoice.com) to **4 to 5 weeks for Carvykti** (Source: carvykti.com). It matters economically because every day of delay increases the likelihood of needing bridging therapy, hospitalization, or, in the worst case, disease progression that prevents infusion altogether, all of which add cost without adding therapeutic value.

Is decentralized or point-of-care CAR-T manufacturing actually cheaper? Available evidence suggests lower costs are possible, though the difference depends heavily on who supplies the viral vector. The VELCART academic trial in India reported a manufacturing cost of **$35,107**, excluding lentiviral-vector cost; the cited review separately describes commercial-product costs near $500,000 (Source: nature.com), and a broader review notes that institutions can further reduce upfront costs by sourcing **research-grade vector preparations for less than $50,000** before a final GMP-grade production run (Source: pmc.ncbi.nlm.nih.gov, so decentralized manufacturing cost still depends heavily on the specific vector-sourcing strategy used.

How does autologous manufacturing cost compare with allogeneic manufacturing? Autologous manufacturing produces exactly one dose per patient per batch, while allogeneic developers claim **100 to 300 or more doses per manufacturing run** from a single donor (Source: allogene.com) (Source: bioprocessintl.com), which spreads fixed manufacturing costs across many more units, though allogeneic products carry the added cost and complexity of GMP-qualified gene-editing reagents that autologous products do not require.

What are the biggest CAR-T supply chain challenges? The dominant challenges are cryogenic and chain-of-custody logistics for a living cellular product (Source: contractpharma.com), a limited number of authorized treatment centers (**135 in the U.S. and 400 worldwide** as of 2024) (Source: pharmavoice.com), and payer approval delays cited by **more than 30% of providers** (Source: pharmaceuticalcommerce.com) as a further source of delay on top of the manufacturing wait itself.

Conclusion

CAR-T manufacturing economics remain defined by a single structural fact: the industry's dominant products are still manufactured one patient at a time, and every cost category examined in this report, viral vector, labor, quality control, cold-chain logistics, and facility overhead, traces back to that "batch of one" model. A review reports commercial-product costs near half a million dollars per dose, while real-world claims data show mean payer-allowed CAR-T product cost of $616,500 and separately identify episodes that can exceed $1 million. Manufacturing and vein-to-vein intervals vary by product and by the interval measured; delays can expose critically ill patients to disease progression before their own manufactured product is ready.

Decentralized point-of-care and allogeneic manufacturing are plausible routes to lower turnaround time and per-dose cost, but neither has yet displaced centralized autologous manufacturing at commercial scale. VELCART reported a 9-day vein-to-vein time and sub-$50,000 combined manufacturing and health-care-resource cost in a small academic setting, with vector excluded from the manufacturing-cost analysis. Allogeneic yields of hundreds of doses remain developer claims. Health systems and payers should therefore compare fully specified, like-for-like cost models and verified turnaround and manufacturing-outcome data before drawing conclusions about COGS reductions.

Tags: car-t manufacturing cost, car-t cogs, vein-to-vein time, decentralized car-t manufacturing, point-of-care car-t, autologous vs allogeneic car-t, car-t supply chain, cell therapy manufacturing, car-t cell therapy cost

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