



Greater Understanding of Cell & Gene Therapies Supports Plan Coverage

Written By Laura Carabello

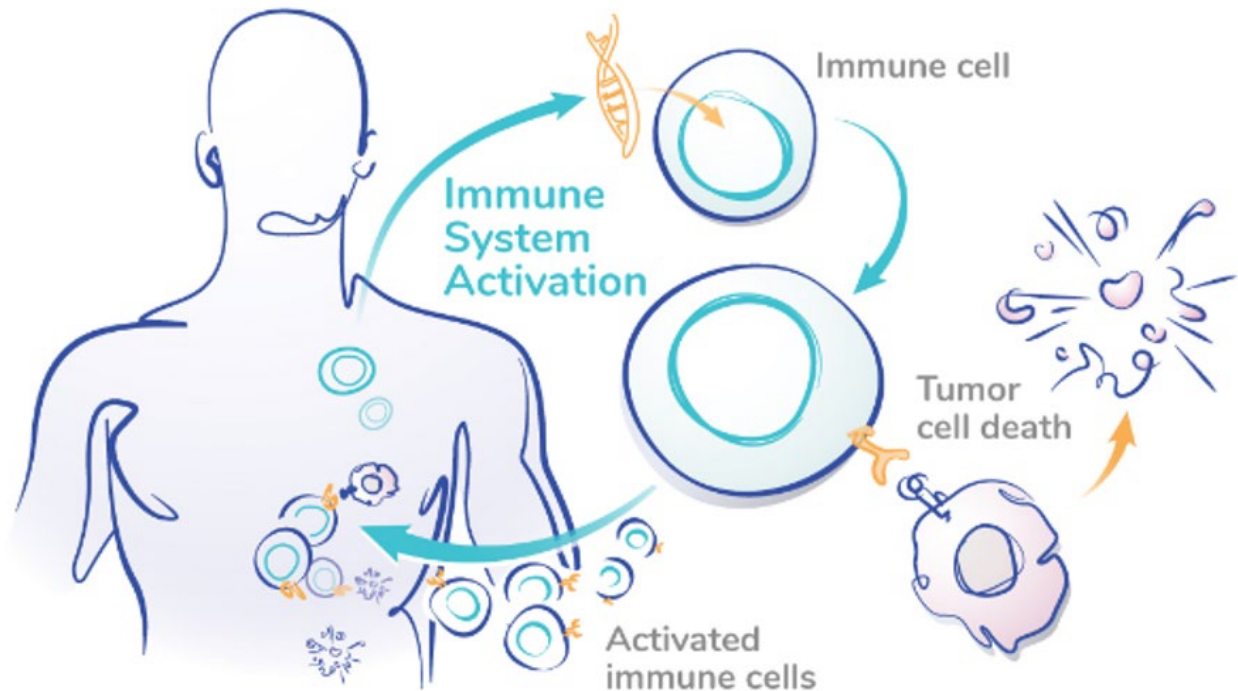
Given that cell and gene therapies are so often paired together, people often think they are interchangeable. While these terms seem similar and both are rapidly advancing areas of modern medicine, they are in fact unique, including their price tags and plan sponsor willingness to cover the cost of treatment. While both are characterized by high costs, they do not necessarily cost the same.

Naga Vivekanandan, Esq., a health benefits consulting attorney with The Phia Group, observes, “Cell and gene therapies (“CGTs”) have moved from the laboratory into mainstream clinical practice, reshaping how serious and often life-threatening conditions are treated. For insurers, these therapies present both promise and peril. Though CGTs are state-of-the-art, transformative treatments that can potentially cure diseases where previously only symptom control was possible, they also carry extraordinary costs and, in their relative infancy, uncertainty about sustainability and long-term outcomes.”

She also comments on the sense of urgency, which is underscored by the market’s explosive growth. The global CGT market topped \$21 billion in 2024 and is projected to grow by 19% annually, making CGT a permanent fixture in benefits planning.

While CGTs offer transformative potential, they create a defining challenge for the self-insurance community, as Vivekanandan advises, “As these treatments quickly become an expected part of both modern benefit design and medicine, a purely reactive approach is fiscally untenable. Proactively building a strategy for network access, cost containment, and risk management is no longer simply an option, but an essential component of responsible and sustainable plan stewardship.

Cell and Gene Therapy



Source: Alliance for Cancer Gene Therapy

Jakki Lynch, RN, CCM, CMAS, CCFA, director of cost containment, Carbon Stop Loss Solutions, proposes that CGTs have the potential to change how we treat many serious diseases, but they are complex and not well understood. She explains that some therapeutic strategies combine both cell and gene therapy, and in such cases, stem cells are harvested from the patient, genetically modified in a laboratory to express a therapeutic gene, expanded in number, and then reintroduced into the patient.

“It’s important to raise awareness about what these therapies are, how they differ, their potential benefits, risks and high costs,” offers Lynch, suggesting that the American Society of Gene and Cell Therapy is an excellent resource for understanding the differences between cell and gene therapy. “FDA-approved CGTs are generally covered benefits under health plans, although coverage depends upon the plan’s specific medical policy or plan coverage definition for each therapy. Approval for individual patients requires the correct diagnosis and meeting all established criteria without any contraindications.”



Naga Vivekanandan, Esq



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¹ Based on medical record review of 573 patients, from multiple employers, referred into the Mayo Clinic Complex Care Program in 2024.

² American Health Policy Institute (AHPI); High Cost Claimants: Private vs. Public Sector Approaches

Assessing the safety, efficacy, and suitability of these therapies can be complex and challenging, especially in clinically intricate cases. A specialized review by a matched, board-certified, and actively practicing physician can offer an independent expert opinion to be considered as documentation for the evaluation of potential plan coverage for the proposed treatment.

UNRAVELING GENE THERAPY

Gene therapies are primarily one-time treatments designed to alter a specific part of the genetic makeup to help treat genetic or inherited diseases. They promise to cure or slow the progression of aggressive, debilitating and often fatal conditions. A section of DNA or gene of interest is packaged within a vector – such as a ring of DNA called a plasmid. This is the vehicle that carries the DNA into the cell.

Once inside the correct cell, the DNA is expressed by the cell's normal machinery, leading to production of the therapeutic protein and treatment of the patient's disease.

Industry visionaries forecast that the future of gene therapy involves expanding applications beyond rare genetic diseases to common conditions like certain cancers, high cholesterol and obesity, with technologies like CRISPR enabling gene editing, not simply insertion.



2025 NY Institute of Technology

CRISPR stands for Clustered Regularly Interspaced Repeats. This new genome-editing technique is so much faster, easier and more accurate than anything that's come before that it's creating a new paradigm for biological research.

Here's how it works. Scientists program a guide RNA on a protein called Cas9 with the address of the targeted gene. The guide RNA directs the Cas9 protein to cut both DNA strands precisely at the correct spot, like a molecular scalpel. A new section of DNA is added to the cell and edited into the original DNA sequence, which now incorporates the characteristics of both sequences.

The CRISPR revolution is already happening in research labs worldwide. For better or worse, every life on Earth will soon be affected by our ability to reprogram the software of life.

Source: Britannica

Lynch describes gene editing as another related approach that uses specialized enzymes called nucleases to modify specific DNA sequences.

"This technique allows for the insertion, replacement, removal, or alteration of DNA at precise locations in the genome to treat diseases," she continues. "This includes Sickle Cell Disease and Transfusion-Dependent Beta-Thalassemia. One notable example is CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), a powerful and targeted gene-editing tool that can simultaneously modify multiple genes."

Source: Mass General Brigham

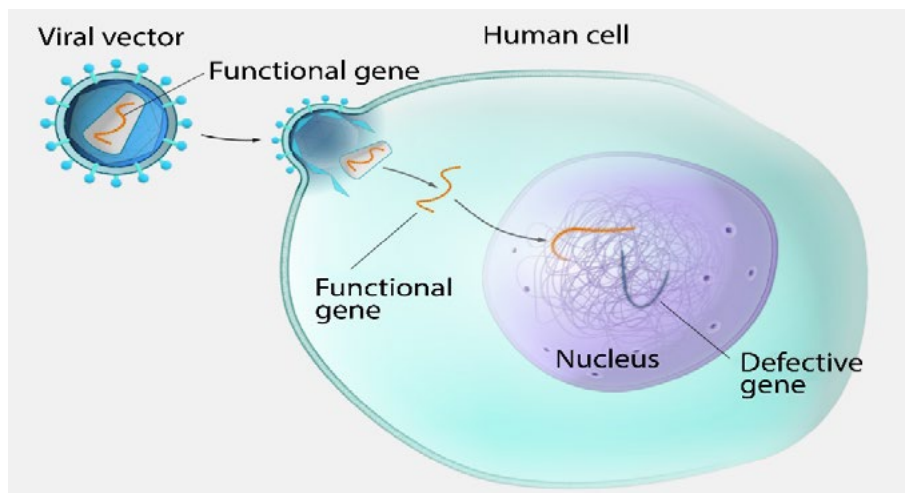


NORMAL RED BLOOD CELL



SICKLE RED BLOOD CELL

Additional and potentially life-saving gene therapies are emerging, driven by rapid advancements in biotechnology, accelerated FDA approvals, significant investment and new delivery methods such as RNA therapeutics that aim to treat diseases at their source by controlling the production of harmful proteins or introducing therapeutic ones.



While challenges persist related to managing expectations for optimized outcomes, affordability of exorbitant price tags and the complexity of navigating new regulatory pathways, ongoing research aims to provide treatments for virtually all rare genetic disorders and beyond. In 2025, advancements include new treatments for genetic blindness, hemophilia, muscular dystrophy and cancer gene editing therapies.

Source: 2025 National Human Research Institute

Gene therapies generally have a higher average cost per dose compared to cell therapies, averaging around \$1 million to \$2 million per dose, with some treatments exceeding \$4 million. The average cost per cell therapy treatment is typically around \$1 million, according to the Institute for Clinical and Economic Review (ICER). However, prices can differ significantly depending on the specific therapy and indication. Some analyses suggest a lower average of \$300,000 to \$500,000 for cell therapies.

As the gene therapy market as a whole is projected to cost \$18.5 billion in the U.S. by the end of 2033, plan sponsors face an unprecedented challenge in deciding which products to include in their plan design.

One way that employers can protect themselves against unpredictable healthcare costs is by purchasing stop-loss insurance. According to Evernorth, this type of coverage is designed for employers who want to hedge against the risk of assuming 100% liability for losses that stem from high-cost claims. As employers utilize stop-loss coverage in conjunction with their self-insured health plan to mitigate high-cost claims for CGTs, this approach can be tailored to cover expenses that exceed a set dollar amount.

While most employers may not have seen the financial impact of CGTs yet, waiting to develop a strategy for these therapies is not a viable option, advises the Business Group on Health (BGH). They say that given that there are more than 3,600 CGTs currently in the pipeline, the number of approved therapies is poised to grow substantially. At this point in time, the majority of coverage decisions are made individually for each therapy, but the patient support structures, and payment mechanisms may be developed for all therapies in this class collectively due to shared challenges about the complex site-of-care considerations and high financial exposure.

BGH advisers insist that existing models, such as Center of Excellence (COE) programs or stop-loss insurance, are not designed for these therapies – despite the advice from other resources and the increased utilization of this approach. According to their survey, 9% of employers indicate that they will have a COE for cell and/or gene-based therapies in 2025, and another 10% are considering it for 2026/2027.



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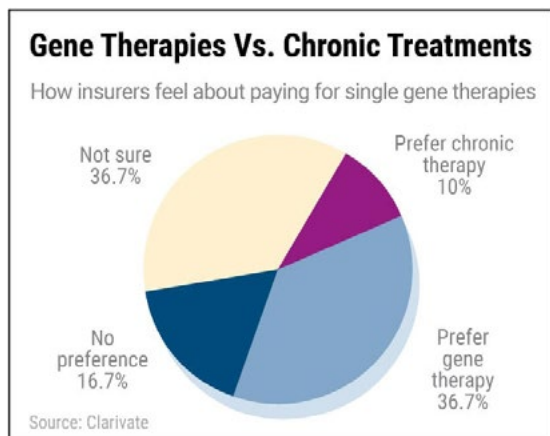


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also caution that there have been few clinical studies on genome editing, a more recent approach than gene transfer that is still being reviewed for potential risks.

Among the setbacks, cancer cases in studies of sickle cell and hemophilia gene therapies renewed safety concerns as reported in the New England Journal of Medicine, including patient deaths in a neuromuscular disease trial.

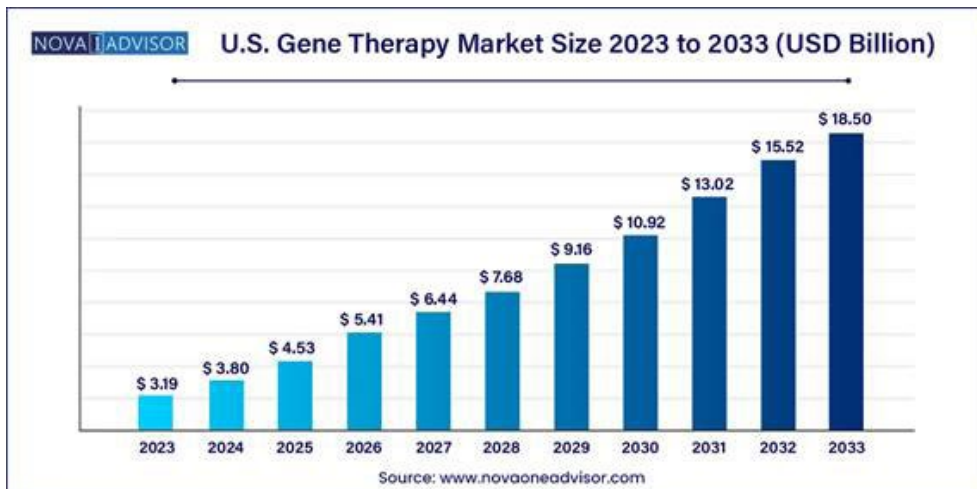
Most recently, the deaths of two patients treated with a Duchenne muscular dystrophy treatment sparked controversy: In early September 2025, the drug developer initiated ongoing efforts to work with the FDA to complete an updated safety labeling for Elevidys, following a temporary halt in shipments and pauses in clinical trials initiated in July 2025 due to safety concerns -- including patient deaths from liver failure. While the FDA allowed the resumption of Elevidys shipments for ambulatory patients in late July 2025, the therapy's future for non-ambulatory patients remains under review.

BE AWARE OF THE RISKS

According to Ways2Well, altering the genetic material raises a danger of bad results. Including the issue that the inserted genes may not function as expected, or they may cause unintended effects. Immune reactions and insertional mutagenesis may occur. Since gene therapy works at the genetic level, the effects for a long period are not known, although additional trials are underway to help evaluate the safety and efficacy of this treatment.

There are also warnings from the National Heart, Lung and Blood Institute of the NIH that while genetic therapies hold promise to treat many diseases, they are still new approaches to treatment and may have risks. Potential risks could include certain types of cancer, allergic reactions, or damage to organs or tissues if an injection is involved.

They point to recent advances that have made genetic therapies much safer, resulting in the FDA approving some gene transfer therapies for clinical use. But they



The gene therapy market potential is also being tested since many carry seven-figure price tags, raising affordability issues. Even when insurers cover treatment, only a few have seen strong adoption. Despite these factors, the market size continues to grow: Estimates suggest a significant increase in FDA approvals, with industry groups projecting around 10-20 new cell and gene therapies annually by year-end 2025 and some anticipating as many as 35 novel therapies on the market by 2026.

While the FDA is pushing for faster drug reviews as part of a new accelerated approval pathway, the agency will consider drug affordability as one of the priorities of its new voucher-based program.



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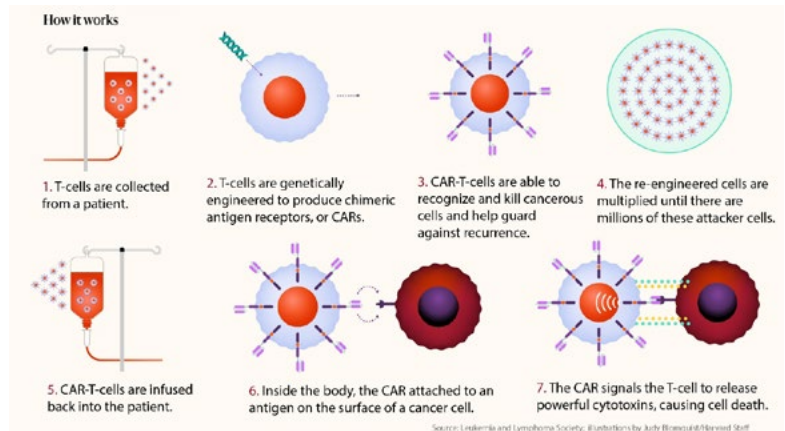
APPRECIATING CELL THERAPY

Cell therapy products place new cells into your body to treat certain health conditions – essentially, the transplantation of healthy cells into a patient to replace or repair damaged or diseased cells. They can be used for many purposes, ranging from treating cosmetic wrinkles to advanced prostate cancer. The goal of cell therapy is to improve the patient’s health by introducing functional cells that can enhance the immune system, regenerate tissues or deliver therapeutic proteins or genes.

Industry observers contend that stem cells represent a type of “holy grail in regenerative medicine.” Since they can grow into any type of cell or tissue, they can potentially repair everything from the heart and bone to the pancreas and brain. Despite increased scientific interest, realizing their full promise has been challenging, and advancements are slow to emerge as drugmakers face multi-level production challenges.



Jakki Lynch



Vivekanandan further clarifies that the hallmark of cell therapy is treatment through actual living cells, taken either from the patient (autologous) or from a donor (allogeneic).

“The goal is repairing or replacing damaged tissue or enhancing the body’s natural ability to fight disease,” she explains. “Gene therapy, in contrast, focuses not on delivering new cells, but on altering the genetic instructions inside the patient’s cells, to repair or replace faulty genes, silence harmful mutations, or introduce new genetic material altogether.”

For plan sponsors who treat cell therapy and gene therapy as separate benefits subject to different protocols, these distinctions matter.

“Clear, unambiguous plan language and participant education are key, and should ideally provide as much information as possible regarding coverages, case management, and ancillary factors such as travel and lodging, particularly since the specialized nature of CGT often means that the necessary treatments are not available locally,” he continues.

“When members understand the value and limitations of coverage, they are more likely to engage constructively in the care process and to have realistic expectations regarding outcomes. Furthermore, for members in need of CGT, benefit ambiguities or disputes can become serious, sensitive issues, especially for employers -- as opposed to traditional insurers, which have no other relationship with the patient.

SPOTLIGHT ON CAR-T CELL THERAPY

One of the more promising developments has been CAR-T cell therapy, first approved by the FDA in 2017. CAR-T-cell therapy recruits the body’s immune system in the fight against cancer. Some

of the sickest patients experience rapid improvement, bringing optimism to people who had given up hope with the failure of one treatment after another.

Vivekanandan further explains, “Unlike chemotherapy, which indiscriminately targets both cancerous and healthy cells, or radiation, which similarly carries significant collateral damage, CAR-T is designed to be highly specialized and precise, reducing or mitigating many of the risks and downsides associated with traditional cancer treatments. Clinical trials and real-world use have shown remarkable remission rates in patients with certain blood cancers who had exhausted every other treatment option; in some cases, individuals who were given little chance of survival achieved sustained remission after a single course of therapy.”

Operationally, the initial infusion is not all that needs to be considered.

“Health plans should expect significant critical-care utilization following the initial CAR-T episode, as evidence suggests that ICU admissions occur in roughly a quarter to a third of infused patients, with a median ICU stay lasting around four days and approximately 18% ICU readmission within 30 days,” says Vivekanandan. “These are costs that are easy to overlook, especially when serving as the baseline to the initial cost of the therapies themselves.”

CAR-T cell therapies have been approved in the U.S. market for several types of leukemia, lymphoma and multiple myeloma. Studies conducted by the American Society of Hematology now support their use earlier in a patient’s disease, rather than after all other treatment options have been exhausted. The FDA has also taken steps to make them more accessible.

Cell therapy’s impact on cancer care is growing, and biotech companies have continued to invest in ways to improve it. Just last year, two new approaches -- known as TCT and TIL cell therapy -- reached the market and may be providing additional options that are now showing up on plan sponsor claim costs. There is even the potential for cell therapy in areas outside, such as autoimmune disease, where promising research from German scientists has sparked a flurry of drug research.

Vivekanandan asserts that market trends indicate that utilization of CAR-T is accelerating, as regulatory approvals have expanded to cover treatments for multiple subtypes of leukemia, lymphoma, and myeloma, dramatically expanding the eligible patient pool. Researchers are also exploring CAR-T’s application to solid tumors – a frontier that could help exponentially more people. As evidence builds and awareness grows, both physicians and patients are increasingly considering CAR-T earlier in the treatment pathway rather than only as a last resort.

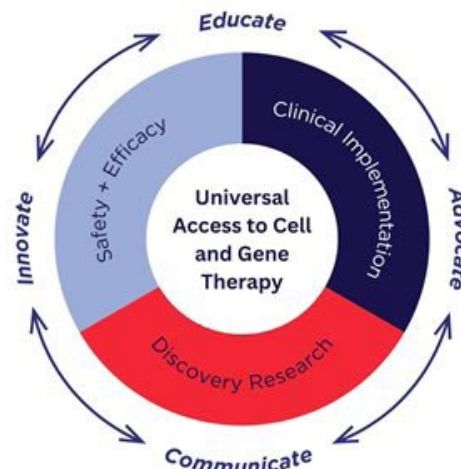


Alarming Rise of Cancer Diagnoses

According to the 2026 Employer Health Care Strategy Survey by the Business Group on Health, cancer remains the leading factor driving employer healthcare costs for the fourth consecutive year. This trend is exacerbated by an increasing number of cancer diagnoses and rising treatment expenses, including immune and cell therapies.

The American Society of Gene and Cell Therapy (ASGCT)

reports that CAR-T cell therapies continue to dominate the pipeline of genetically modified cell therapies, accounting for 55% of these therapies. The ‘other’ category, which includes less common technologies like TCR-NK, CAR-M, and TAC-T, makes up 25%.



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“Notably, 83% of CAR-T therapies are being developed for cancer-related indications, though some are also targeted at non-oncology diseases, with a few exclusively focusing on conditions such as lupus, multiple sclerosis, and HIV/AIDS,” notes Lynch.

FACTOR IN COST DYNAMICS

He cautions that the cost dynamics are sobering, adding, “Acquisition alone often ranges between \$373,000 and \$465,000 per infusion, excluding hospitalization and any complication-related costs - which, given CGT’s relative novelty, can be unexpectedly high. Total per-patient expenditures can exceed \$500,000, and severe side effects like cytokine release syndrome can cost an additional \$30,000 to \$56,000 to manage. Medicare inpatient cases alone averaged around \$498,700, with observed costs hovering over \$1,000,000.”

Medicare payment data show that CAR-T is still predominantly inpatient (about 79%), and the average inpatient CGT cost exceeds the average outpatient cost by approximately 21%.

Vivekanandan illuminates the discussion, “Like all services, however, private payers can expect to be billed significantly more than the Medicare rate.

Even a conservative reference-based pricing model can expect to pay at least 25% more than these averages.”

She makes it clear that for self-funded employers, this presents a significant risk: “Specific or even aggregate stop-loss deductibles can be reached with even just one claim, and the likelihood of ‘special risk limitations,’ or lasers, being placed on individuals who are in need of CGT is high. Unlike chronic drug costs, which accumulate gradually, CAR-T concentrates the cost into a one-time event, creating unique financial and actuarial challenges.”

For this reason, CAR-T therapies are often seen as the most tangible example of the “double-edged sword” of medical innovation – potentially curative treatments that can transform lives, but at a price that tests the limits of benefit design and risk management.

Some adverse effects can appear during stem cell therapy, including the possibility of immune rejection of donor stem cells, tumor formation and unintended development of stem cells into inappropriate cell types. However, stem cell therapy constitutes a relatively safe procedure, although it must be carefully monitored.



Landmark Florida Legislation

On July 1, 2025, the state quietly passed Senate Bill SB1768, a law allowing physicians to offer patients certain stem cell treatments that have not yet been approved by the FDA, for use in treating specific indications and subject to regulatory compliance.

This under-the-radar change raised eyebrows from clinicians, patients and policymakers across the country. Many see this as a long-overdue step toward expanding treatment options for patients who are not satisfied with the current standard of care.

As the demand for stem cell therapies continues to grow worldwide, this legislation is expected to bring about many differing options across the entire healthcare ecosystem. For physicians, it introduces an opportunity to offer patients new treatment alternatives while also shining a spotlight on the complex intersection of innovation, oversight and clinical ethics, especially in a space that has long lacked regulatory clarity.

Source: 2025 Next Gen Biomed



CAR-T CELL THERAPIES: RISING HIGH-COST CLAIMS RISK

Of all FDA-approved cell and gene therapies, Kirby Eng, R.Ph., Chief Clinical Officer, OutcomeRx, maintains that Chimeric Antigen Receptor T-Cell therapies (CAR-Ts) have emerged as the most commercially successful—and the most frequently flagged by health plans and self-insured plan sponsors as a clear high-cost claims risk.

“CAR-Ts are personalized, one-time cancer treatments that require a complex sequence of pre-treatment requirements, patient-specific cell manufacturing, intricate logistics, and intensive post-treatment monitoring, often including extended hospitalization,” he explains. “The result is frequently a total claim cost exceeding \$1 million per case, covering both the therapy and administration requirements.”

Eng points to several market dynamics that are expected to further increase CAR-T claims exposure:

- FDA approvals for earlier lines of treatment
- Expanded manufacturer production capacity
- Recent removal of Risk Evaluation and Mitigation Strategy (REMS) requirements.

“Although currently limited to hematologic (blood) cancers, CAR-Ts are advancing in clinical trials for solid tumors and autoimmune diseases, which represent significantly larger patient populations,” he continues.

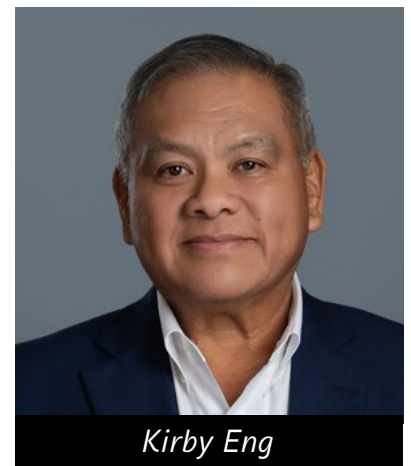
While value-based/outcome-based and extended payment programs exist, they are generally negotiated between manufacturers and health plans, making them largely inaccessible to self-insured plan sponsors.

“It becomes an imperative strategy for plan sponsors to seek a solution designed to provide cost-effective coverage that specifically addresses the complexities related to these therapies,” he suggests. “Companies such as OutcomeRx are uniquely positioned to work closely with brokers and benefits consultants to structure effective coverage solutions for their clients in a manner that mitigates financial exposure and obtains access to comprehensive patient support services.”

As CAR-T indications expand—particularly into earlier treatment settings and beyond hematologic cancers—Eng says the question for self-insured plan sponsors is no longer if they will see a CAR-T claim, but when and how often. Therefore, he recommends proactive strategies that balance financial exposure, cost containment and personalized care management as essential to protecting both the plan sponsor and their covered employees.

Lynch concurs: “CAR T-cell therapies are complex, high-touch, and extremely costly treatments. To manage these expenses effectively, a comprehensive cost-management strategy must account for the entire care continuum, including post-treatment monitoring, rehabilitation, and any additional care related to complications or side effects.”

She further observes that the process is intensive and carries significant risks, including serious adverse events such as cytokine release syndrome and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)—a potentially life-threatening neurological condition that often requires hospitalization.



Kirby Eng

Lynch also points out that the average wholesale acquisition cost (WAC) for currently FDA-approved CAR T-cell therapies is approximately \$525,000.

“However, this figure excludes significant ancillary costs such as facility and professional fees, invoice markups, and the management of comorbidities during the cell manufacturing period,” she reports. “Facility claims data indicate that while the therapy list price accounts for a substantial portion of expenses, it does not reflect the full financial risk burden. Our claims analysis shows that average total billed charges can reach \$2.2 million per treatment episode—highlighting the substantial cost exposure beyond the drug itself.”

NAVIGATING THE COSTS OF CAR-T

CAR [T-cell therapy] is the most expensive Medicare diagnosis-related drug, reports the Chronic Lymphocytic Leukemia Society, citing these cost components of direct costs:

- Apheresis (a process that draws blood and, using a cell separator, collects T cells before returning the remaining blood to the body)
- Biopsies
- CAR T-cell production
- Hospital stays
- Imaging studies
- Medicines
- Other related expenses may include housing, travel and caregiver support





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CAR T-cell therapy is only accessible at a certified center, requiring the member to stay no farther than 2 hours away from the center for at least 4 weeks. Inability to work may result in lost income, further escalating the total costs.

Certain plan designs may stipulate out-of-pocket expenses that aren't covered, including deductibles and other expenses, while others may pay for inpatient stays but not for certain medicines or medical devices

ARE CAR-T THERAPIES WORTH THE COST?

Doctors and patients are literally awestruck by the results of CAR-T therapies. Specialists at the pediatric and young adult cancer cell therapy program at Dana-Farber/Boston Children's Cancer and Blood Disorders Center report astonishing results: "tumors melting away over weeks or even just days and people who appeared to be on death's door getting up and reclaiming their lives. One leukemia patient who almost died while receiving the therapy was cancer-free and snowboarding within two weeks.

According to the Harvard Gazette, the therapy has been most effective against leukemia, lymphoma, and myeloma, which together accounted for 9 percent of U.S. cancer cases last year, affecting 187,000 Americans. One important new frontier is to

extend these gains to solid tumors, but equally important is the reality that CAR-T doesn't work for everyone.

Researchers report that remission rates are currently between 50 and 90 percent, depending on the condition, and cancer is still the largest single cause of mortality for those undergoing the treatment. They also cite a major concern with the severity of side effects: a 2024 study blamed side effects for almost 12 percent of non-cancer deaths among CAR-T patients. Sometimes, the body overreacts to treatment and can cause severe nausea, vomiting, rapid heartbeat and hallucinations among the symptoms. Another dangerous side effect affects the brain, causing temporary confusion in mild cases and coma in serious ones.

However, they say that for patients who have exhausted other options, CAR-T-cell therapy, even with the side effects, is almost always worth trying. By moving CAR-T from a last resort to a second-line treatment, they appear confident that this treatment has the potential to clear cancer from the body.

The graphic features a dark blue header with the 'aequum' logo in white lowercase letters. Below the logo, the title 'Advocacy in Action' is written in a large, bold, white sans-serif font. The main body of the graphic is light yellow and contains three columns of information. Each column has a circular icon at the top: a rocket for 'Efficient Claim Resolution', a money bag for 'Unmatched Savings', and a map of the United States for 'National Expertise'. Below each icon is a short paragraph of text. At the bottom of the graphic, there is a horizontal line with the phone number 'P 216-539-9370' and the website 'www.aequumhealth.com'. Below that is a disclaimer: 'No Guarantee of Results - Outcomes depend upon many factors and no attorney can guarantee a particular outcome or similar positive result in any particular case.' and a copyright notice: '©2024 aequum, LLC. All Rights Reserved'.

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Another word of restraint emanates from doctors and scientists at The American Society for Hematology, the world's largest professional society of clinicians and scientists who are dedicated to conquering blood diseases. They concede that not all patients are cured, and at least half will relapse and still require further lines of therapy.

They also acknowledge the uncertainty surrounding the true costs for administering these relatively new treatments, issues that are also tied to questions about reimbursement. In August

2019, the Centers for Medicare and Medicaid Services (CMS) issued a final rule that raises payments for new technologies, including CAR T-cell therapies, from 50% to 65%.

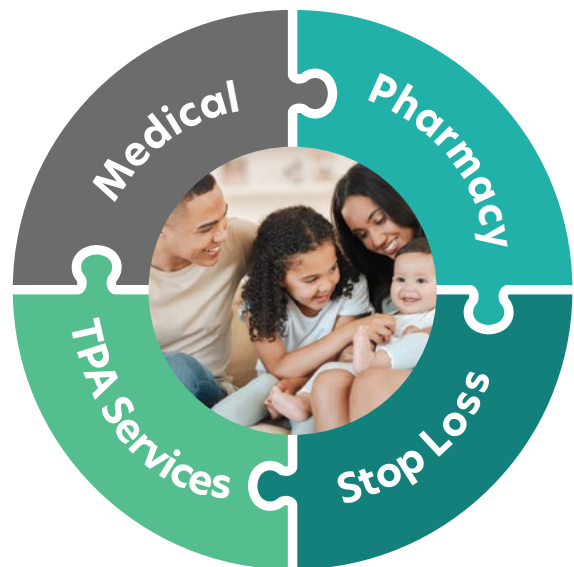
While healthcare experts welcomed this decision, some expressed concern that it does not provide enough relief for hospitals. As more of these therapies are FDA-approved, they worry about whether health systems can afford to pay for these therapies and whether they're going to be adequately reimbursed by insurance companies.

CELL VS. GENE THERAPY: IS ONE BETTER?

This is not a question of one over the other. Receiving a cell or gene therapy is a very personalized experience that depends upon the individual situation. These treatments are only used in certain situations, and the best option is the one that takes into account a variety of factors, including:

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- Previously used medications
- Treatment goals
- Insurance coverage status
- Personal preferences
- Cost

There are also marked differences in the scope of treatment:

Hereditary illnesses are caused by changes in certain genes, and gene therapy works best to manage these conditions. It fixes and adds genes to replace broken and missing ones. It is reported that there are substantial and powerful effects in treating cystic fibrosis and muscular dystrophy.

Stem cell therapy is mostly used to treat diseases and injuries that have resulted in tissue damage and degeneration. Some examples of these disorders are osteoarthritis and heart disease. Stem cell therapy doesn't fix genetic abnormalities. It helps tissues mend and grow again.

IMPROVING ACCESS TO THERAPY

In their decision-making process of whether or not to cover CGTs, employers are following the results of the CMS Cell and Gene Therapy (CGT) Access Model, which aims to improve the lives of people living with rare and severe diseases by increasing access to potentially transformative treatments. It is a multi-year, voluntary model for states and manufacturers to test whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies increases Medicaid beneficiaries' access to innovative treatment, improves their health outcomes, and reduces healthcare costs and burden to state Medicaid programs. The model underscores CMS's commitment to accelerating access to innovative therapies, improving patient health, and tying payment to outcomes.

On July 15, 2025, CMS announced that 33 states, along with the District of Columbia and Puerto Rico, will be participating in the CGT Access Model. Of these, seven states and the District of Columbia have applied for and been awarded Cooperative Agreement funding. The initial focus of the model is on access to gene therapy treatments for people living with sickle cell disease, a genetic blood disorder.



Source: 2025 CMS.gov. Centers for Medicare and Medicaid Services

Furthermore, the U.S. Food & Drug Administration (FDA) recently removed its Risk Evaluation and Mitigation Strategies (REMS) designation from CAR T immunotherapies. REMS is occasionally applied to drugs with serious potential safety issues, requiring providers to pursue and document more robust mitigation strategies.

Removing the designation is often a routine regulatory change. This shift signals that both the regulatory and medical communities are comfortable that providers can rely on CAR T's prescribing information to manage risks and benefits.

STRATEGIES FOR MANAGING CGT COSTS

The initial question employers need to ask themselves is whether to cover these therapies to begin with. Vivekanandan advises that from a design perspective, considerations include whether coverage aligns with fiduciary responsibilities and member expectations, the cost of these services, the employee population and whether this coverage is right for the plan as a whole, medical management techniques, and how stop-loss will treat a claim.

"For some plans, excluding these therapies might make sense in the near term, while for others, partial coverage with strict oversight might strike a better balance," she says.

"Others still may choose to broadly cover CGT as necessary for employee well-being, in the same way that specialty drugs are typically covered."

Because these therapies are unique in their structure and delivery, plan language should be drafted precisely.

"Ambiguity around whether a given item of CGT falls under a medical or pharmacy benefit, how complications are handled, or uncertainty regarding medical necessity or the experimental nature of services to begin with can create member confusion, legal risk for the plan, and even reputational risk for the employer," he expounds. "Additionally, as the market evolves and science progresses, a given plan's initial CGT coverage intentions may change."

For those who do decide to cover these therapies, the question then becomes how to manage their impact responsibly.

Vivekanandan suggests that stop-loss coverage remains a primary tool for protecting against catastrophic claims, but employers should carefully review policies for exclusions or limitations related to CGTs and coverage for complications in addition to the therapy itself. She cautions that stop-loss is not a permanent solution.

"Diagnosis-specific disclosures aside, in the first policy year after incurring a large CGT claim, most stop-loss carriers will apply a Special Risk Limitation, or 'laser', excluding that individual's claims from future stop-loss reimbursement," he notes.

Another strategy is contracting with certain providers or with vendors who specialize in directing and managing patient utilization.

"This can help maintain consistent protocols and, ideally, relatively favorable pricing," he continues. "However, there may be a stigma attached to contracting efforts on an as-needed basis rather than doing so proactively. One multi-center study found that approximately 35% of privately insured patients' coverage required a single-case agreement, which delayed financial clearance and lengthened decision-to-vein time. Patients who never reached infusion had markedly worse survival rates, and when this was due to an inability to reach a negotiated rate, it signals an avoidable administrative failure."

Anecdotally, few employers are likely to view engaging and paying a vendor, or taking the time to find, negotiate, and contract with CGT providers on a proactive basis, as a prudent expenditure of resources. Instead, employers will typically rely on their claims administrators to handle CGT needs reactively, despite their potential time-intensive, yet time-sensitive, nature.



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“In this environment, a variety of financing and risk-sharing models have emerged to address the challenges of paying for CGTs,” says Vivekanandan. “Employers looking to move beyond traditional stop-loss will need to assess these new approaches when contracting with health plans, PBMs and other partners in the healthcare ecosystem.”

While the importance of coverage decisions cannot be understated, the key challenge for plan sponsors is to develop proactive strategies to address access to quality care, support for the duration of treatment, medical complexity and long-term implications of CGTs for employees' well-being.

Lynch captures response to these challenges, adding, “In an effort to address the upfront high cost of care and uncertainty of the clinical outcomes, we have explored several innovative proposed payment models in the form of therapy product carve-outs, pay over time methodologies, clinical warranty templates based on retrospective payment adjustments, and cost rebates tied to patient outcomes.”

She asserts that outcomes-based contracts are the preference, but they come with ambiguity secondary to challenges in establishing transparent and verifiable clinical outcomes criteria and require substantial resources for tracking outcomes. They may not address the total cost of care with provider markup, administration charges, and additional costs for potential complications, and there are only a few manufacturers accepting innovative payments for their therapies.

“Currently, to ensure value and financial sustainability, we have adopted a comprehensive cost-management approach,” she states. “This includes evaluating the entire episode of care—from pre-treatment workup and inpatient monitoring to post-treatment rehabilitation and management of complications—to accurately assess and manage the total cost of care.”

Beyond ensuring proper utilization and validating plan coverage for treatment to provide patients with the most effective care—thereby supporting optimal member outcomes and plan benefits, she advises that managing costs through well-structured, financially sound facility contracts is essential.

“Not all facility rate contracts offer the same value,” she informs. “We conduct a thorough analysis and aim to secure all-inclusive, financially sound-rate agreements and value-based contracts—where available—with manufacturer-designated Centers of Excellence to ensure cost-effectiveness and high-quality outcomes.” ■

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