Transformative Treatment

Payers facing the need to find innovative ways to pay for increasingly costly cell and gene therapies and track efficacy

Written By Bruce Shutan

Game-changing cell and gene therapies have emerged as new and groundbreaking ways to treat and sometimes cure diseases that previously had no treatment. Common targets include cancer, Alzheimer's, HIV, cardiovascular disease and arthritis.

For self-insured health plans that cover these categories, the eye-popping price they pay for making them available is expected to capture more of their attention and force the need for innovative solutions.

Since many of these therapies treat rare diseases that affect a limited number of individuals and the development of such therapies can take years, it's not surprising that the price tag is often extremely high for manufacturers to realize a return on their investment. These treatments present enormous financial challenges for payers who also are expressing concern about unknown long-term efficacy.

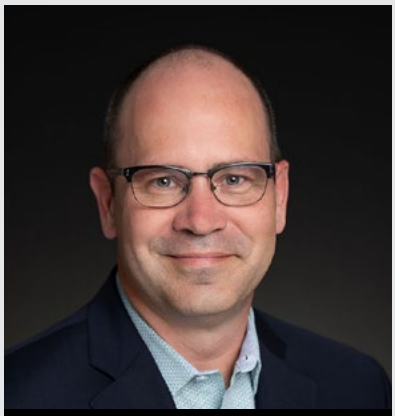
Other than using traditional reinsurance vehicles, there haven't been viable ways for self-insured health plans to absorb these costs. Better understanding the financial risks posed by these costly therapies is just the start of how actuaries will help mitigate this expense.

They also believe the risk of a public-relations nightmare may be simply too great when assessing the hypersensitive nature of certain ailments relative to the rewards that can be reaped from witnessing substantial and life-changing clinical improvement.

EYEING STICKER SHOCK

These issues are top of mind for SIIA's leadership. Shaun Peterson, VP of stop loss for Voya Financial who's on SIIA's board of directors, says the Drug Pricing Task Force he chaired focused on "the process of evaluating how best to support SIIA membership as we collectively face the challenges presented by new developments and approvals in this area." This work resulted in the release earlier this year of the SIIA Drug Pricing Best Practice Guide.

That effort also kick-started efforts to educate the marketplace about this increasingly high-profile area. Since cell therapy is more "transplant adjacent," much of it involves bone marrow and non-solid organ transplants, while gene therapy is actually a pioneering development, explains Jay Ritchie, president and CEO of Tokio Marine HCC Stop-Loss Group who moderated a SIIA crowdsourcing event on this subject.



Jay Ritchie

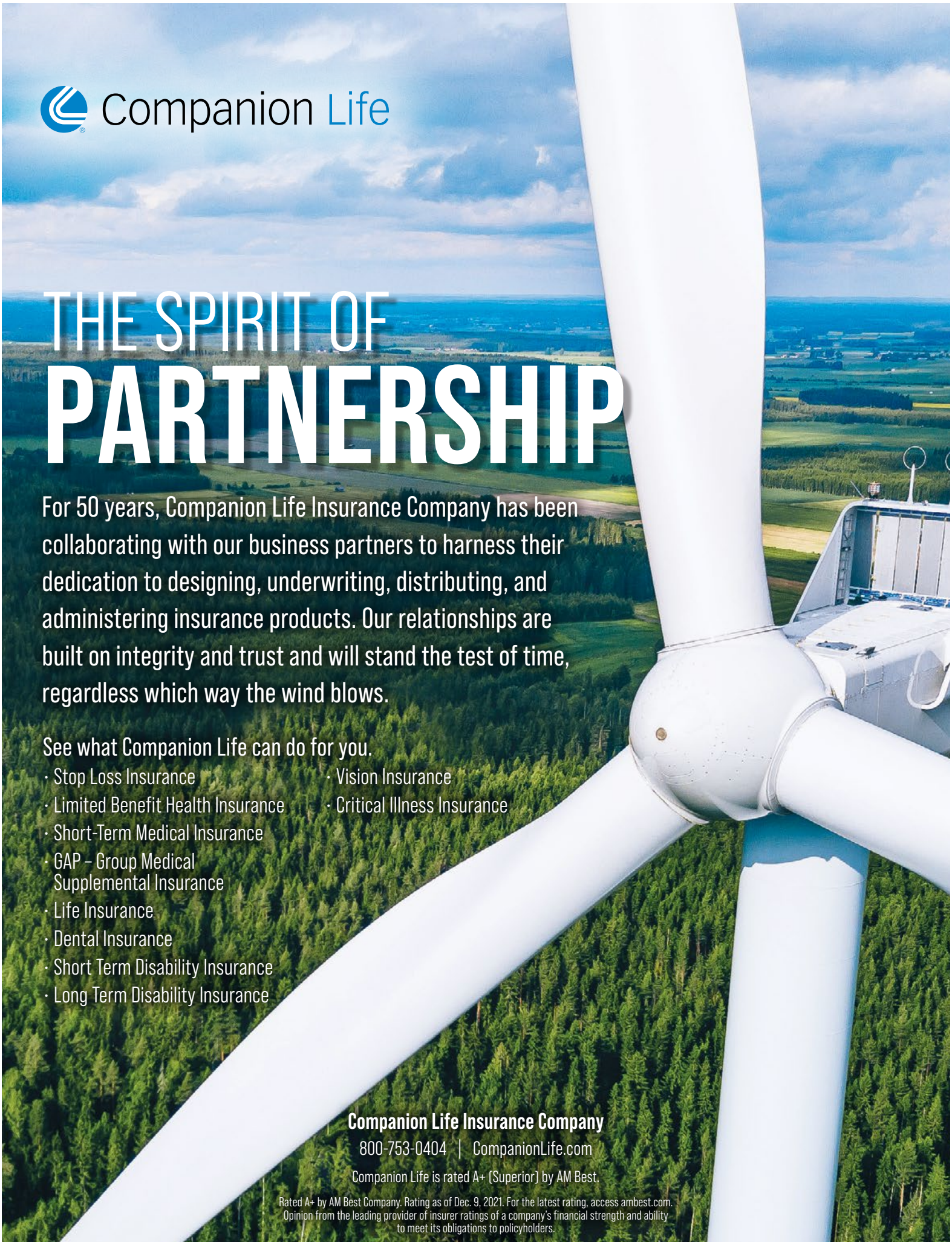
"Cellular therapy is taking the way we currently treat something and making it a better treatment, so it's just that continual focus," he says, "whereas gene therapy truly is not treating the disease anymore; it's solving the disease. It's advertised to be curative. We will find out if they actually are curative over time."

The first cell therapies brought to market about seven years ago raised eyebrows with price tags in the $400,000 to $500,000 range, recalls Mehb Khoja, president of Medical Risk Managers, a stop-loss consultant, underwriter and actuary and wholly-owned subsidiary of BCS Financial for which he is also chief actuary. But the bar for sticker shock was raised even higher in 2018 to 2019 when he says the first gene therapies were introduced at between $850,000 and $2.1 million with a hemophilia treatment that followed with an expected price tag of $4 to $5 million.

About 50 new gene therapies are projected to reach a market that will swell to more than $25 billion over the next few years – a frenetic pace that's not expected to cool down, observes Michael J. Baldzicki, chief brand officer for AscellaHealth.

"We're going to see an explosion of innovation in this area with huge price tags," he says. Since a single event can be financially devastating to a self-insured plan sponsor overnight, he foresees smaller employer groups attempting to manage these risks, while reinsurers struggle to even forecast for that impact.

These costly therapies are very focused on rare types of cancer, including myeloma, non-Hodgkin's lymphoma, acute leukemia, B-cell lymphoma and ovarian cancer, Baldzicki says.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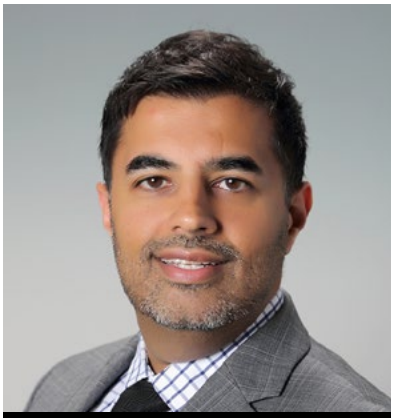
"We know oncology is tough to manage," he observes. "You can't strip that away from the oncologist tied to his hospital."

As such, they're expected to have significant price tags.

Surya Singh, M.D., SVP, medical delivery services and chief medical officer of Emerging Therapy Solutions, reports that there's "a very rich pipeline" of cell and gene therapies in development. Of particular note based on recent events is a ex vivo treatment platform for delivering gene therapy based on lentivirus, which is the platform for the recently approved treatment of beta thalassemia, an inherited blood disorder, and efforts to treat sickle cell disease that are expected late next year or in early 2024. "The headline that everybody's paying closest attention to is hemophilia, both A and B," he adds.

In addition, Singh references the importance of an announcement in the summer of 2020 about the need for more longitudinal and follow-up data for the first hemophilia gene therapy as "a major event for the market," which now expects these reviews could take up to seven years.



Mehb Khoja

Two treatments with the most in-market, longitudinal experience among chimeric antigen receptor T-cell treatments known as CAR T therapies are Yescarta and Kymriah. Stem cell transplants for patients with lymphomas, leukemias and multiple myeloma are considered a predecessor of those therapies.

There also are additional uses for T-cell therapies on the horizon, such as post stem cell transplant for lymphoma to treat lymphoproliferative disease.

The other costly therapies, which he says are garnering more attention because of similar sticker-shock inducing price tags in the seven-figure range, are in vivo viral vector-delivered gene therapies.

One with the longest time since launch and in-market experience is Luxturna, which is an intraocular injected treatment for patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Another is Zolgensma, which treats spinal muscular atrophy in children who are younger than two years old.

REIMAGING REINSURANCE

Given the propensity for sticker shock, industry observers are concerned about reinsurers punting on the cell and gene therapy category, altogether, and in the process, abdicating their role.

"I think the stop-loss and the reinsurance community will by all means exclude individuals who have the identified conditions that can be treated with gene therapy," according to Khoja. "If a stop-loss carrier or reinsurer is looking at an opportunity today, and there's somebody who has beta thalassemia, they're probably going to exclude them because that person is probably a likely candidate to have the gene therapy for $2.8 million. So, they will probably laser the person."

One way to avoid some of the pricing pitfalls is to implement innovative tools that everyone agrees upon, he says, along with the way that the data is going to be monitored at the time the contract is signed. "What happens now is that the reinsurer community, also known as second-dollar payers, ends up paying for the vast majority of the dollars spent on these therapies because most of the expenditure is above the attachment point on the reinsurance that they sell," he notes.

Most self-funded employers have historically relied on stop-loss policies to cover cell and gene therapies that on average cost anywhere from $350,000 to more than $3 million. "Once that market creeps up, and all of a sudden you have 70 gene therapies, there is no way the hospital market can meet that demand," Baldzicki cautions.

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Given the inherent difficulty of managing this substantial risk, he says manufacturers and payers have come under increasing pressure to enter into value-based agreements. AscellaHealth has been examining various pilots with life-science companies, brokers and reinsurers like Marsh to determine where the market is at, as well as where it's headed, with loan-based programs to recover or recoup costs related to the impact of cell and therapies. Another area to consider for helping manage those burgeoning costs involves international sourcing from the establishment of centers of excellence abroad, he adds.

BUILDING IN WARRANTEES

Concern about the unknown long-term efficacy of these therapies also needs to be addressed. If there are treatment failures, for example, Singh says it's important to track when they actually occur. One suggestion is the possibility of a bifurcated system whereby higher payments would be made for successful treatments and lower amounts for cases where the treatment didn't work as well as intended.

Ultimately, he notes that these are more targeted treatments that are being implemented along the way to adoption of personalized, precision medicine.

"When you're for the most part treating people who either were previously unaddressed or had a very high failure rate with current therapeutic options, the ability to be able to show cost effectiveness at a higher price tag is increased," according to Singh.

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Surya Singh

At such high prices, Khoja believes payers increasingly want reassurances that cell and gene therapies work and will continue to work into the future. "Imagine you bought a TV from Costco and it doesn't work anymore," he surmises. "Well, you take it back to Costco and get your money back. The self-insured employer, health plan or reinsurer – whoever's on the hook – is going to want a mechanism to see if this stuff still works down the road. You're buying something with the idea that you're eliminating future expense on this issue, and if that's not the case, then we have to revert back to the old or current forms of payment."

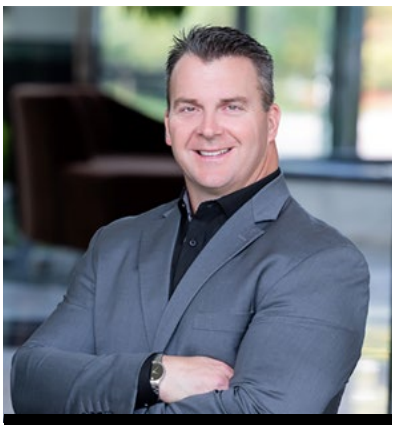
Drug manufacturers are building in warranties for this very purpose as they bank on these costly treatments to cure certain serious conditions, Khoja reports. But he says it will be on the payer to essentially follow through and measure whether they work and where they don't work, as well as paving the way for recoupment of their dollars.

Mindful of the potential for enormously improved outcomes for segments of the workforce, in some cases there could be an extraordinary return on investment in terms of employee productivity.

For example, Ritchie notes that half of people who are stricken with the sickle cell red blood cell disorder they inherit from their parents aren't able to work full time. "This is potentially a cure for sickle cell that brings a large population of what was considered unable to work into the productivity category," he says.

There are easily 15 to 20 gene therapies in the pre-FDA approval stage, according to Ritchie. "We're going to start seeing gene therapies kick off in a material way in the next 12 months," he opines, hastening to add a caveat. "The one thing I see in the industry right now is it's still a bit of a Wild West because there are a lot of different solutions, but there's not been a lot of experience to figure out the best solutions."

To offer a better sense of just how rare this treatment area is, Baldzicki notes that the criteria to be on gene and cell therapy is quite rigorous. "You can't drink and smoke. You can't have this. You can't do that. It's not a free-for-all that you can just try gene and cell therapy," he explains. "Most physicians and patients are going to wait. There's probably about six, eight, maybe 12 options in a therapeutical area because once you try a gene and cell therapy, you're done. You can't go on another one. So they're going to make sure they try the most appropriate one."


Mike Baldzicki

As an intimate observer of these claims, Baldzicki can't help but recognize the humanity associated with such expensive, life-altering treatments. "You actually get a tear in your eye when you're seeing babies and so forth with these staggering, debilitating, rare immune deficiency diseases, and they're cured," he says. "But the financial risk and wraparound of that is very impactful to an employer group. It's exciting, but I think it's scary at the same time that we've got to have an evolution to really tie in technology that will lead to revolutionize how we look at containing costs in these areas."

Bruce Shutan is a Portland, Oregon-based freelance writer who has closely covered the employee benefits industry for more than 30 years.