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## PAYMENT MODELS

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Radiation ReimbursementHOW VALUE-BASED CARE IS CHANGING  
RADIATION ONCOLOGY FOR THE BETTER

Courtney Dean, MBA

**TODAY'S EVOLVING HEALTH CARE** landscape has created a challenging environment for radiation oncologists—one that makes revenue streams unpredictable and increases the administrative hassle associated with the delivery of quality care. Medicare radiation reimbursement rates declined 24% from 2008 to 2017, with an initial 7% to 8% additional payment cut projected for 2022 based on an American Society for Radiation Oncology (ASTRO) analysis of the 2022 Medicare Physician Fee Schedule,<sup>1</sup> which was subsequently mitigated by The Protecting Medicare & American Farmers from Sequester Cuts Act signed in December 2021.<sup>2</sup> Cuts to radiation therapy reimbursement are recommended yearly by CMS.

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## PRACTICE TRANSFORMATION

Telehealth at Minnesota Oncology:  
Tackling COVID-19, Educating Patients,  
and Overcoming the Weather

Mary Caffrey

**THE RISE OF TELEHEALTH** during the COVID-19 pandemic has been an important topic at oncology conferences, with surveys showing various levels of satisfaction on the part of providers and patients, as well as concerns about disparities in the level of access to technology.<sup>1,2</sup>

Reimbursement barriers to telehealth adoption came down during COVID-19, allowing oncology practices to see for the first time where its use made sense and where it did not. The American Society of Clinical Oncology (ASCO) responded with guidelines for telehealth use, suggesting that the technology likely will be part of the treatment landscape for good.<sup>3</sup>

A consensus is emerging. When it comes to diagnosing cancer, telehealth can never replace the in-person visit. But during a pandemic, it is highly useful—and perhaps better—for some elements of cancer care, because it can increase the number of touch points in areas such as survivorship care and nutrition, which would otherwise require a separate visit to the office.

For some practices, however, telehealth could prove a game changer when dealing with a problem that no quality measure or technology upgrade can fix: the weather.

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Kite Pharma officials say a new manufacturing facility in Frederick County, Maryland, will help ensure timely turnaround of customized products for chimeric antigen receptor T-cell therapy.

## IMMUNO-ONCOLOGY

With Approval for Axi-cel in Second-line  
on the Horizon, CAR T-Cell Therapy  
Poised to Enter New Phase

Mary Caffrey

**WHEN THE FDA APPROVED** the first 2 chimeric antigen receptor (CAR) T-cell therapies in late 2017, the scientific world cheered. Cell-based gene therapies had arrived, offering hope to patients who had run out of options to manage their blood cancers.

CAR T-cell therapy promised to transform cancer treatment; then-FDA Commissioner Scott Gottlieb, MD, heralded “a new frontier in medical innovation with the ability to reprogram a patient's own cells to attack a deadly cancer.”<sup>1</sup>

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# With Approval for Axi-cel in Second-line on the Horizon, CAR T-Cell Therapy Poised to Enter New Phase

MARY CAFFREY

## CONTINUED FROM COVER

Tisagenlecleucel (tisa-cel; Kymriah; Novartis) was approved in August 2017 for treating patients with pediatric acute lymphoblastic leukemia (ALL).<sup>1</sup> Two months later came the approval of axicabtagene ciloleucel (axi-cel; Yescarta; Gilead/Kite Pharma) for treating patients with relapsed or refractory large B-cell lymphoma (LBCL).<sup>2</sup>

Both anti-CD19 treatments were approved for patients who had received at least 2 prior lines of therapy. By definition, these were very sick patients, and often their aggressive cancers meant there was little time to waste. But when CAR T-cell therapy first moved from clinical trials and into the real-world setting, the medical miracle collided with reality: those early days were rife with stories of frustrating delays as payers and institutions alike worked to get treatments approved before patients' health deteriorated.

CAR T-cell therapy represented something new for patients and clinicians—and it was new to the reimbursement infrastructure as well. The cost of 1-time treatments was so high—\$475,000 for tisa-cel and \$373,000 for axi-cel—and the financial risk to hospitals so great, that in early 2018 a revenue cycle manager told *Evidence-Based Oncology*<sup>™</sup> (*EBO*<sup>™</sup>) each case required decision-making at the highest levels of his institution, a situation he hoped would “lessen over time.”<sup>3</sup>

The lessons of that learning curve remain fresh as Kite Pharma prepares for a major milestone. The FDA will soon act on its supplemental biologics license application for use of axi-cel as second-line therapy in relapsed or refractory LBCL. A target action date is set for April 1, 2022.<sup>4</sup> This follows the results of the ZUMA-7 trial presented in December 2021 at the American Society of Hematology Meeting & Exposition (ASH). Lead investigator Frederick L. Locke, MD, of Moffitt Cancer Center in Tampa, Florida, showed that axi-cel quadrupled event-free survival (EFS) compared with the current standard of care (SOC), which includes high-dose therapy and autologous stem-cell transplant (ASCT).<sup>5</sup>

Approval of axi-cel for patients with LBCL who had failed only 1 therapy would potentially boost the number of patients eligible for axi-cel treatment by 11,000 just in the United States, according to data compiled by Kite Pharma (email to *EBO*<sup>™</sup>). Kite Pharma CEO Christi Shaw has said the number of patients eligible for the treatment would roughly double, and Shaw and others from Kite Pharma say they expect the number of patients treated in second line to rise gradually, the same way the uptake of CAR T-cell therapy in third-line treatment increased over time.<sup>6,7</sup>

Alex Herrera, MD, a hematologist-oncologist at City of Hope in Duarte, California, who introduced Locke's presentation at ASH 2021, noted that phase 3 findings from the TRANSFORM trial showed significant second-line benefits in LBCL from the CAR T-cell therapy lisocabtagene maraleucel (liso-cel; Breyanzi, Bristol Myers Squibb). The study results showed that liso-cel produced a risk reduction of 65% in EFS compared with SOC.<sup>8</sup>

Taken together, “The studies do suggest that CAR T-cells likely have a role as a second-line therapy,” he said in an interview. In both studies, patients receiving CAR T-cells had better outcomes, and there were better patient-reported outcomes.

“The hope, as a treating physician, is that we will be able to use these exciting therapies for our patients with primary refractory or early relapsed aggressive B-cell lymphoma to improve outcomes and their quality of life,” Herrera said.

## Is the Health System Ready for CAR T in the Second Line?

From Kite Pharma's perspective, progress in manufacturing, payer relations, and collaboration with the 111 institutions that administer axi-cel puts the CAR T landscape light years ahead of where it was in 2018. Some cancer centers are described by Kite officials as “well-oiled machines” when it comes to CAR T-cell therapy administration.

However, commercial payers and Medicare are not the same. Although Medicare reimbursement has improved since 2018, a gap remains between what CAR T-cell therapy costs and what Medicare pays. How institutions will address this as a new category of patients seeks CAR T-cell therapy remains to be seen. An Avalere Health analysis of Medicare's most recent reimbursement update discusses a change that puts CAR T-cell therapy and other immunotherapies in the same Medicare Severity Diagnosis Related Group (MS-DRG), which the analysis authors say could have dramatic effects at some hospitals.<sup>9</sup>

*EBO*<sup>™</sup> spoke with Kite Pharma's Robert Shelley, vice president for global market access and pricing, and Mary Lynn Carver, vice president and global head of public affairs. They highlighted items they say point to a smoother uptake for axi-cel in second-line treatment:

- Despite the projected increase in the number of patients being treated with axi-cel, the number of institutions administering the treatments will not rise sharply; these cancer centers are now experienced in the reimbursement process.
- Kite Pharma has published medical policies with 91% of US commercial payers; some policies are not published but access is confirmed.
- Kite Pharma's experience with its second CAR T-cell therapy, brexucabtagene autoleucel (Tecartus), approved in 2020 for mantle cell lymphoma and in October 2021 for relapsed or refractory B-cell precursor ALL, shows that payers can rapidly incorporate new CAR T-cell therapy indications.<sup>10</sup> In the ALL indication, “we achieved over 85% of commercial coverage within the first quarter of launch,” Shelley said.
- Investments in the manufacturing process—including a new facility—will keep turnaround times down even as the number of patients receiving axi-cel grows.

Of course, Shelley said, snags do occur. Coding errors happen, and occasionally a new employee at a health plan is unfamiliar with CAR T-cell therapy. And although the process may be easier than it was in 2018, one thing is the same. For commercial plans, “the reimbursement pathway to get funding for treating these patients is often under a single-case agreement,” Shelley said.

Will this change as axi-cel and eventually other CAR T-cell therapies are approved in second- or even first-line treatment? Shelley said there's been discussion of this happening, but it's challenging from both sides. These are still patients with rare diseases, he said.

“In 2022, do I expect to see a move to global case rates from the payer community? Probably not,” Shelley said. “As we move toward 2023? Perhaps, as we start to see some of the national payers moving in that direction—because the price of CAR T is well-known at this point.” »



**HERRERA**  
Alex Herrera, MD, medical oncologist-hematologist, City of Hope, Duarte, California.



**SHELLEY**  
Robert Shelley, vice president for global market access and pricing, Kite Pharma.



**CARVER**  
Mary Lynn Carver, vice president and global head of public affairs, Kite Pharma.

## Medicare Reimbursement Improves, Still Falls Short

From the beginning, the biggest questions institutions had about CAR T reimbursement involved Medicare. Would they get paid? How much? And how long would payment take? The cancer centers that had run clinical trials in tisa-cel and axi-cel—and were thus best equipped to treat patients after approval—wincing at the losses that accumulated as Medicare payments came in far below total costs, which for some patients could reach \$1 million once hospital costs were included.<sup>11</sup>

Medicare's opening act with CAR T was a bust: CMS' early "pay for performance" agreement with Novartis for tisa-cel, in which the manufacturer would be paid only if the treatment worked within a month, was quietly withdrawn over ethics concerns, and the long journey to a national coverage determination began. Any progress individual states were making with regional Medicare Administrative Contractors was halted. In the interim, Medicare's billing framework was not set up to deal with something such as CAR T-cell therapy, so CMS defaulted to the MS-DRG for bone marrow transplant, which paid just \$43,094.<sup>12-14</sup>

Although Medicaid covered a fraction of eligible patients, some states refused to cover CAR T-cell therapy at all.<sup>15</sup> Since then, changes to the Medicaid Best Price rule and value-based reforms from CMS could make it easier for Medicaid to pay for these treatments.

In March 2019, Locke, who was a coauthor on the pivotal ZUMA-1 trial, told an audience at the National Comprehensive Cancer Network Annual Conference that what Medicare was paying providers for CAR T-cell therapy was not sustainable. "If it's not figured out soon, we will not be able to do this for Medicare patients," he said.<sup>13</sup>

By fiscal year (FY) 2021, CMS created an MS-DRG for CAR T-cell therapy, raised the average national reimbursement base rate to \$239,933, and incorporated the use of add-on and outlier payments to bring Medicare's total payment closer to list prices. But a gap remained, and Avalere Health projected the FY 2022 reimbursement update will cause the net loss to widen again, to \$30,988, even though base rates rose to \$246,958.<sup>9</sup>

What's more, the FY 2022 changes under the Inpatient Prospective Payment System final rule adds new procedure codes under the MS-DRG and expanded the category from CAR T-cell therapy to "Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies."

The update was seen by some as a sign of CMS' flexibility toward new therapies,<sup>14</sup> but, Avalere Health warned in its analysis that "the financial impact of these changes will vary by hospital and in some cases may continue to fall short of fully recognizing provider costs of treatment."<sup>9</sup>

The ongoing gap, the authors wrote, "sometimes fails to cover total hospital costs, with potential negative impacts on provider uptake and patient access."

## Long-term Survival Data Are Strong

When it works, CAR T-cell therapy seems like something from a science fiction novel: a treatment manufactured with a patient's T cells is infused back

into the body to harness the immune system in the fight against cancer. Not long after its approval, there were discussions about whether giving CAR T-cell therapy earlier—when patients had not received as much therapy—would improve the success rates.<sup>16</sup>

Axi-cel, now approved for third-line treatment of follicular lymphoma, will likely be the first of several CAR T-cell therapies approved for use in second-line treatment. In addition to the liso-cel findings, results at ASH 2021 covered CAR T-cell therapies in multiple myeloma, such as additional phase 2 data for ciltacabtagene autoleucel (cilta-cel) that showed strong responses when used in second-line treatment.<sup>17</sup>

Payers' initial hesitancy toward CAR T-cell therapy concerned its lack of a track record, given the cost. But as long-term data have come in, CAR T-cell therapy has outperformed other available options in overall survival.

**The difficulty of getting patients to transplant may prevent some physicians from even referring patients for the procedure. If axi-cel is approved in the second line, one task will be educating physicians that most eligible patients successfully complete the chimeric antigen receptor T-cell procedure; the hope is that more doctors will be willing to refer their patients.**

Besides the EFS data from ZUMA-7, patients who took axi-cel were also 2.5 times more likely to be alive after 2 years without the need for additional treatment than those who received SOC (40.5% vs 16.3%).<sup>5</sup> Meanwhile, data published in October 2021 found that patients in ZUMA-1 had a 2-year survival rate of 54%, compared with 20% for patients enrolled in SCHOLAR-1, which was a retrospective study of similar patients treated with salvage chemotherapy.<sup>18</sup>

In his presentation at ASH 2021, Locke highlighted another important point taken from the ZUMA-7 data. Of the patients randomized to axi-cel, 94% successfully received CAR T-cell treatment; in comparison, only 36% of those randomized to SOC received high-dose therapy and ASCT.

This aspect of comparing axi-cel with ASCT is often overlooked, Carver said. The difficulty of getting patients to transplant may prevent some physicians from even referring patients for the procedure. If axi-cel is approved in the second line, one task will be educating physicians that most eligible patients successfully complete the CAR T-cell procedure; the hope is that more doctors will be willing to refer their patients. "That's a paradigm shift," she said. "We really have to work with referring physicians to make sure that they understand this."

Herrera said the fact that so many patients never make it to transplant has been "a huge problem."

From the patient's perspective, he said, "Imagine having this option that you're striving for (transplant)—that, until recently, was the main curative treatment that we had for relapsed or refractory aggressive B-cell lymphoma. Except that we can't get you there most of the time. That's pretty tough."

"So, [if] a much higher proportion of patients are going to be able to get CAR T-cells than arrive at transplant, from the perspective of the patient, I can only imagine that at least patients feel like they've got that shot—they were able to have a potentially definitive therapy to cure the disease."

Because some patients who had ASCT in second-line later need CAR T-cell therapy, the hope is that by offering CAR T-cell therapy first, the toxicity of ASCT is thus avoided. (Conversely, some patients who have CAR T-cell therapy in second-line may relapse and need further treatment, and ASCT might be an option). Shelley said health economics research is under way to explore the financial impact of all these possible outcomes.

## Manufacturing and Time to Infusion Are Keys to Success

During December's ASH meeting, Michael R. Bishop, MD, director of the hematopoietic stem cell transplantation program at the University of Chicago presented findings from the phase 3 BELINDA trial, which tested the effectiveness of tisa-cel in second-line treatment. Unlike ZUMA-7 and TRANSFORM, the BELINDA study did not meet its end point. In a news briefing, Bishop said that although there were other differences between the 2 trials, he believed a key advantage for ZUMA-7 was the time to infusion was much shorter than in BELINDA—a median time of 27 days vs 52 days, respectively.<sup>19,20</sup>

Time to infusion is how long it takes for a patient's cells to be removed from their body through leukapheresis, brought to a manufacturing facility and transformed into the lifesaving treatment, and finally infused back into the patient. In ZUMA-7, patients did not have any bridging therapy, only steroids—which could be another reason the results differed from BELINDA. Once a patient is identified as a candidate for CAR T-cell therapy, any delays—whether due to manufacturing, scheduling, or trying to get approval from a payer—give the aggressive lymphoma time to advance.

Herrera said there could be many factors that go into a decision to give chemotherapy ahead of CAR T-cell therapy. "A lot of patients get bridging chemotherapy before they get their CAR T cells, and that's going to remain a reality," he said. But Herrera agreed that delays can cause problems—there was a recent stretch when patients experienced scheduling delays for leukapheresis, although it has improved recently. "That really puts us in a bind," he said.

City of Hope has made significant investments in CAR T-cell therapy administration, Herrera said, and he doesn't find payer coverage a "limiting issue." He agrees that production is "a critical factor" and the availability of manufacturing slots is very important. "This is an aggressive disease, and it can be difficult to control. If you have to wait several weeks just to get a collection, and then several weeks

to have production—that can be a real challenge. And it's going to result in patients needing to get chemotherapy.”

This is where CAR T-cell therapy is unlike taking a pill or having a traditional infusion—this is a *process*, so finding efficiencies in that process will be key to improving patients' chances of survival along with better science. Carver said with this in mind, Kite Pharma has built a 279,000 square foot manufacturing plant in Frederick County, Maryland, which is scheduled to be fully operational not long after the April 1, 2022, target date for axi-cel's indication in second-line treatment.

At Kite Pharma, Carver said, “there's a great deal of [research and development] in CAR T related to manufacturing, in the quality of the manufacturing and the quality of the T cells themselves. We've been doing a lot in automation...and our turnaround is very good—it's best in class in the industry.”

Still, Carver said, Kite Pharma continues to try to make the process even faster. “The automation that's coming online in Maryland will help that,” he said.

In 2019, the *Baltimore Business Journal* reported that Kite Pharma's expenditures on the Maryland project would be \$85 million.<sup>21</sup> But if the investment pays off, one analyst estimates the second-line indication for axi-cel could be worth \$1.5 billion, according to Fierce Pharma.<sup>7</sup>

### Engaging Payers at the Start

Shelley said Kite Pharma has been preparing for ZUMA-7 and the growth in the patient population for several years. “We've staffed up appropriately on a number of support functions with case managers [who] work with our hospital network to facilitate patient care and do all the logistics and individual manufacturing, scheduling and handling—with the flexibility to include weekends,” he said.

In engagements with payers ahead of FDA approval, Shelley said payers want to know more than just the clinical results. They want specifics on the manufacturing capacity, turnaround times, technology advancements, and “all the pieces of what is really a complex patient journey,” he said.

Kite Pharma is engaging with senior leaders at payers to address concerns about handling this new wave of patients. “We are working with payers to prepare the CAR T space for growth. This indication is going to be much bigger than anything they've seen before,” Shelley said.

Given the importance of turnaround time—and the findings at ASH—does Shelley think payers understand that they also have a business stake in being efficient?

“Absolutely,” he said. “The dollar figure for cell and gene therapies is so high, and they want to make sure that the product is going to perform—that patient responses are going to be consistent with what we saw in clinical trials.”

Payers want to experiment with different financing mechanisms, including value-based payment models developed by MIT's NEWDIGS initiative.<sup>22</sup> Although Medicaid accounts for approximately 5% of the payer mix, the removal of the Medicaid Best Price barrier is significant, Shelley said.

“There's a high level of interest,” he said. Payers “do see themselves as part of the care team,” and

believe CAR T-cell therapy has been transformative for patients with late-stage cancer, he said. Kite is also working with employers who want to make sure they're getting what the coverage pays for. However, experimentation with alternative payment models is still in its infancy, Shelley said. Questions abound on how to align clinical end points, capture data, and administer agreements.

### Next Up: CAR T as First-line Therapy

The scientific world isn't waiting on FDA for its next challenge: bringing CAR T-cell therapy to first-line treatment. ZUMA-12, a phase 2, single-arm study presented at ASH 2021 found even better outcomes for high-risk patients given axi-cel: the 12-month overall survival rate was 91%.<sup>23</sup>

*EBO*<sup>™</sup> asked Herrera: how will physicians decide which patients with LBCL should be treated CAR T-cell therapy from the start?

“It's tricky,” he said. “It's always been difficult to define a high-risk enough population that you're willing to forego chemotherapy.” For most patients, CAR T-cell therapy will likely be used starting in second-line treatment.

The question, Herrera said, is, “What's the next step? Is it as consolidation after frontline therapy for patients who aren't in a complete molecular response according to minimal residual disease testing? Or will we identify a population where we can attempt CAR T-cell therapy as a frontline therapy?”

In ZUMA-12, he said, patients in the study exhibited chemoresistance before they were given axi-cel. “Is there a group of patients we can identify who should be getting this as first-line therapy? I think that remains to be seen,” Herrera said, “but I anticipate that these questions are going to be asked.” ♦

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