Cost of Anti-Cancer Therapies Demands New Strategies for Decision-Making, Shared Responsibility, Communication s the cost of cancer care continues to climb and more costly cutting-edge therapies like chimeric androgen receptor (CAR) T-cell gene therapy are approved, finding solutions to address financial toxicity continues to challenge even the most robust cancer programs.

Although CAR T-cell therapy has shown promise in many patients who have run out of standard treatment options, the cost is often upward of \$1 million per course of treatment.<sup>1,2</sup> The side effects are extensive and sometimes severe, and the complexities of the therapy's administration require an interdisciplinary approach for success.

# The Pharmacist in Immunotherapy

Pharmacists play a crucial role in successfully implementing CAR T-cell programs. As payers push to treat CAR T-cell similarly to bone marrow transplantation for reimbursement, pharmacy directors must be well-versed in various payment models. Institutions are learning how to be more prepared when making operational changes based on new drugs entering the market.

Julie Kennerly-Shah, PharmD, MS, MHA, is the assistant director of pharmacy at The Ohio State University Comprehensive Cancer Center—Arthur G. James Cancer Hospital and Richard J. Solove Research Institute in Columbus—one of the first cancer centers in the country to use CAR T-cell therapy in clinical practice.

Though Dr. Kennerly-Shah and her team are focused on providing the best care for their patients, including using the most novel therapies, she is concerned, like most in oncology, that if the cost of immunotherapy drugs continues to increase, the trajectory is not sustainable. The larger concern, of course, is that there will be treatments that can help patients but that will be out of reach for most. A contributor to cost is not only the price tag for the CAR T-cell therapy itself but also the cost of extended hospital stays. "It is well documented that it is much more cost effective to deliver care in the outpatient setting when possible," Dr. Kennerly-Shah said.

### **Cost-Cutting Strategies**

Dr. Kennerly-Shah oversees a team of clinical pharmacists who are responsible for working directly with physicians in the inpatient and outpatient settings to determine the most clinically effective and cost-effective therapies for their patients who have been diagnosed with cancer. In addition, she facilitates the Hematology Oncology Pharmacy and Therapeutics Committee (P&T Committee) responsible for making formulary decisions determining which cancer agents will be available to providers for cancer treatments and what restrictions—if any—will be placed on those medications. The committee is actively seeking and implementing innovative solutions to keep costs down.

The P&T Committee's strategies include examining prescribed treatment plans and weighing the costs with the benefits. For example, if a drug costs twice as much but provides minimal extra benefit, should it be used? Are the treatment benefits sufficient to offset the cost? The committee looks at whether clinical



Julie Kennerly-Shah, PharmD, MS, MHA.

changes can be used to offset cost, asking "What can be done on an outpatient versus inpatient basis to reduce overall healthcare costs?" The committee is also focused on improving the use of biosimilars and on how best to approach the reimbursement process for these drugs.

"Historically, if you received a diagnosis of lung cancer, you received the regimen that was first-line for lung cancer. Now we use biomarkers and targeted therapies to drive a more personalized approach to cancer therapy," Dr. Kennerly-Shah said. This targeted approach is limiting some of the physical toxicities from cancer treatment, and it is extending duration of life for patients.

One of the major challenges to accessing immunotherapy, however, is economic. "We are really excited about these novel agents, and we want to be able to offer our patients the absolute best cutting-edge therapy," Dr. Kennerly-Shah said. "We are also faced with acknowledging that financial toxicity is real, and patients have legitimate concerns about the cost of their cancer therapy the same as they would have concerns about the cost of their cholesterol medication. Balancing the two issues has been quite the process over the last 5 to 10 years."

#### **Planning for Outpatient Care**

A contributor to cost is not only the price tag for the CAR T-cell therapy itself, but also the cost of extended hospital stays. "It is well-documented that it is much more cost-effective to deliver care in the outpatient setting when possible," Dr. Kennerly-Shah said. "Each night in the hospital that we can save is significant. We have a multidisciplinary group that worked hard to develop processes and procedures where we could see these patients every day in the outpatient setting."

"In fact, patients would prefer to be outpatient, if possible, but it does take significant infrastructure and planning on the part of the facility to be prepared to deliver CAR T-cell therapy in the outpatient setting," said Dr. Kennerly-Shah.

# **Biosimilars and the Electronic Health Record**

The P&T Committee is actively working on how the team at Ohio State University Comprehensive Cancer Center can better incorporate biosimilar medications into its portfolio of offerings by looking at how the committee can work with IT teams to enable their Epic electronic health record to better facilitate the use of biosimilars. When treatment plans are built in Epic, it needs to be easy to substitute a biosimilar for a reference product.

"When a provider wants to start a patient on a specific combination of medications, a treatment plan is pre-built in Epic to include all of those medications," Dr. Kennerly-Shah said. "The challenge with biosimilars is that there are multiple biosimilars on the market. One insurance company may prefer one biosimilar; another insurance company may prefer another." With generics, one can easily substitute another generic and the billing works the same, but this not true in the case of biosimilars.

For biosimilars, providers must submit a request and a bill to the insurance company that is specific to that biosimilar. Dr. Kennerly-Shah is working with the P&T Committee and with Epic to find a solution that makes it easy to interchange biosimilars based on which products a patient's insurance may prefer.

### **Patient Communication, Decision-Making**

Another challenge is communicating to patients that they may be put on a biosimilar at some point during therapy. Dr. Kennerly-Shah said that, so far, they have been communicating to the patient that "there's a biosimilar on the market. You may be put on the reference product or the biosimilar, and from the patient's perspective, they don't really feel a difference. From the care team's perspective, these drugs are considered similar enough that it doesn't make a difference in clinical outcomes."

"Having that conversation up-front with patients is important [so] that they understand the difference between a reference product and a biosimilar and a generic, for example," she added. "Typically, we use generics as a frame of reference for patients, acknowledging that it is not exactly the same as having a brand name and a generic substitution."

Biosimilar education is often provided by the pharmacist who is going to be talking to patients about their regimen. "Oftentimes it comes up when the reference product is being denied by the insurance company and we are talking to patients," Dr. Kennerly-Shah said. The pharmacist informs the patient that he or she is going to send a prescription for the biosimilar and expects it to work similarly.

Sometimes a decision is based on the cost of one cancer therapy versus the cost of another that is not a biosimilar and that is a different regimen entirely. "Say you have a new product on the market and it has a three-month difference in overall survival. Have that conversation with the patient regarding the potential cost of this therapy versus that one," Dr. Kennerly-Shah said. "Patients are becoming much more in tune and not only receptive to those conversations, but patients are expecting those types of conversations to occur. They come in wanting to know the cost of therapy. They're very concerned about the financial toxicity, particularly elderly patients tend to be very concerned about the burden they would be placing on their family knowing that they could have significant medical bills upon passing."

This shared decision-making typically includes the physician, the patient, and the patient's family members or caregivers. Pharmacists are often asked to participate in these conversations due to their unique understandings of the clinical and financial implications of one therapy versus another.

### **Data and Analysis to Better Inform Care**

Long-term goals for the P&T Committee include plans for a more robust economic analysis that takes into account the total cost of care. "Oftentimes we are focusing on what is the cost of the medication, which is really important, and it is a huge driver of cost in oncology care. However, it is important to also take into account the cost of toxicities as new therapies come to market," Dr. Kennerly-Shah said. "Future plans include economic analyses that include not just the cost of the therapy, but all the other ancillary costs associated with that therapy that also contribute to the overall cost of care. And how can we then measure one therapy's effectiveness and cost compared to another from an economic standpoint?"

The team at the Ohio State University Comprehensive Cancer Center-James tracks the cost of drugs per patient per day in the inpatient and outpatient settings, as well as reimbursement, continuously evaluating reimbursement compared to drug cost. The team also tracks the number of patients for whom they have been able to utilize patient assistance programs and the overall number of dollars associated with those programs.

"A great number is the amount of free drug, essentially, that we've been able to facilitate for our patients. It is an astounding number annually from working directly with manufacturers and getting patients enrolled in either a co-pay assistance program or a free-drug program with the manufacturers," Dr. Kennerly-Shah said.

A full cost analysis is needed in every cancer program, large or small, in order to deliver cost-effective and quality care to all patients. "I would encourage all cancer programs to be actively looking at not only drug costs, but also building an infrastructure for economic analysis that looks at overall cost of care. When you think about current pending legislation and the Oncology Care Model, we are really moving toward a system that looks at how we can cost-effectively provide cancer therapy to patients as a whole. And that includes not just drug costs, but inpatient stay, outpatient stay, additional visits associated with toxicity, etc.," Dr. Kennerly-Shah said.

"It is important for anyone who provides any amount of significant oncology care to really start thinking about the overall cost of care, and how they are going to build a team to do these economic analyses. There are references like the Institute for Clinical and Economic Review that do great economic analyses, but there's nothing like your own data to see how much a specific diagnosis is costing within your own system."

Amy Hindman is a freelance writer with more than 10 years of experience writing in technology, healthcare, and oncology.

#### References

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# Association for Community Cancer Centers Financial Advocacy Services Guidelines

The Association for Community Cancer Centers (ACCC) has developed the Financial Advocacy Services Guidelines to support the goal of proactively addressing financial issues along the cancer care continuum to help patients gain access to high-quality care for a better quality of life. These guidelines have been developed with the input and guidance of the Advisory Committee for the ACCC Financial Advocacy Network and financial advocates working on the front lines of care. As the healthcare landscape continues to change and the role of oncology financial advocates evolves, ACCC offers these guidelines to assist programs in strengthening their financial advocacy services and to complement the resources available through the ACCC Financial Advocacy.

## ACCC Immuno-Oncology Institute

The ACCC Immuno-Oncology Institute is the only initiative dedicated to educating multidisciplinary teams to go beyond a clinical understanding of immuno-oncology and tackle real-world implementation issues. With the care of patients on immunotherapies now extending beyond the cancer team, the ACCC Immuno-Oncology Institute is at the forefront of developing critical education to empower healthcare professionals across care delivery settings. Learn more at accc-cancer.org/ immunotherapy.