



INNOVATIVE APPROACHES IN PATIENT-CENTERED CANCER CARE

A WHITE PAPER FROM THE **ONCOLOGY THERAPY
ACCESS** WORKING GROUP

No one is ever prepared to hear that they have cancer. But with the help of innovative treatment approaches, more Americans than ever before can successfully deal with their new diagnosis.

Arriving at new life-saving treatments doesn't just happen, though. It requires interest and investment, decades of research, and a paradigm shift in the way physicians think about cancer treatment. Above all, it requires a patient-centered approach to care.

INNOVATION IN CANCER CARE

Innovation in cancer care entails a combination of policy support, dedicated funding and committed researchers. In recent years, the United States has seen these three elements align, spurring a boon in cancer innovation.

In his 2016 State of the Union, President Barack Obama declared his support for a "Moonshot" initiative to eliminate cancer through accelerated research efforts. Congress then pledged \$1.8 billion over seven years "to make more therapies available to more patients."¹ The Cancer Moonshot also aims to improve cancer prevention and detection.

The commitment of federal funding ensures ongoing support for clinical trials to study breakthrough cancer treatments. Trials can broaden access and options for under- or uninsured people. They also can help researchers move innovative ideas from labs into clinics, offering tangible treatments for people fighting cancer. As a result, patients and clinicians today have exciting new treatment options, including immunotherapy.



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INNOVATION IN CANCER CARE

**POLICY
SUPPORT** +

**DEDICATED
FUNDING** +

**COMMITTED
RESEARCHERS**





Immunotherapy

Immunotherapy is one treatment approach that has changed the paradigm for cancer patients. It's a biologic medicine – made of living cells – that harnesses the body's own immune system to fight off cancer. It's most often used to treat melanoma, lung cancer and bladder cancer.² There are several varieties of immunotherapy, including vaccines, checkpoint inhibitors and CAR T-cell therapy.

The checkpoint inhibitor is the most well-known type of immunotherapy, largely because of President Jimmy Carter. He successfully beat cancer using the treatment, which overrides the body's built-in inhibitions, unleashing the full power of the immune system.


While immunotherapy can be lifesaving, patients' expectations sometimes exceed the medicine's capabilities. Explaining the risks and limits of immunotherapy is an important part of the larger

treatment conversation between doctors and their patients. Access challenges remain and, despite its potential, immunotherapy is often out of reach for patients, especially those in rural areas.

CAR T-Cell Therapy

Immunotherapy alters the way one's immune system naturally works within the body. In comparison, CAR T-cell therapy involves extracting T immune cells, genetically altering them in a laboratory, then infusing the altered cells back into the patient. The altered T cells, equipped with chimeric antigen receptor (CAR), then bind to cancer cells and kill them.³

The revolutionary treatments are for non-Hodgkin's lymphoma and leukemia;⁴ they have the potential to dramatically change the course of cancer care for children and young adults. In addition, CAR T-cell therapy has shown promise in treating certain other childhood cancers.



Despite the revolutionary way in which CAR T-cell therapy could change cancer treatment for hundreds of thousands of patients, gaps in billing approaches and reimbursement continue to inhibit access. The Centers for Medicare and Medicaid Services has had an evolving approach to payment issues, with a downstream effect on patient access. The lack of clarity and robust reimbursement may deepen disparities and even hinder access for patients who live outside of academic medical centers. And regardless of location, patients with high-deductible health plans or minimal coverage plans may also face access challenges because of high out-of-pocket costs.

Precision Medicine

Unlike immunotherapy or CAR T-cell therapy, precision medicine is an innovative approach rather than an innovative treatment. Precision medicine is, simply, personalized medicine. Precision medicine involves looking at the genetic change that a patient's tumor undergoes and making treatment decisions based on that data.

Dissimilar to other treatment approaches, precision medicine is not reliant on the type or location of the cancer. Rather, it involves making medical decisions for each individual patient based on his or her personal health history, variability in genes, comorbidities, lifestyle and environment.⁵ This type of targeted, personalized cancer care can yield better treatments, fewer side effects, improved outcomes and saved lives.

Sorting and treating patients based on their type of cancer rather than the location of their cancer may be a difficult approach for many to adopt. It requires shifting thought processes, strategizing beyond any specific therapy and embracing a patient-centered mindset.

CHALLENGES INHIBITING CANCER CARE

Innovative treatments and novel approaches will continue to redefine cancer treatment. Meanwhile, research to find cures is ongoing. In fact, the U.S. government spends billions of dollars supporting efforts aimed at both objectives.⁶ Yet, ironically, cancer patients often can't benefit from the tremendous investment of tax dollars.



“Precision medicine represents patient-centered care in its purest form: providing the right treatment to the right patient at the right time.”

Arturo Loaiza-Bonilla, MD

TRADITIONAL CLINICAL PATHWAY

Specific Cancer Type



Specific Treatment Approach



PRECISION MEDICINE

Cancer Diagnosis



Diagnostic Testing



Consideration of Patient's Medical History, Comorbidities, Lifestyle



Personalized Treatment Plan



Health insurers are increasingly using rigid utilization management policies to save money by limiting access to tests and treatments. When applied to diagnostics, these barriers keep physicians from knowing necessary information about their patients' situation. The barriers also delay patients' access to prescribed treatments that could cure their cancer and save their lives.

Veering from Clinical Pathways

Following a standardized course of care, a clinical pathway, based on one's type of cancer is the historically accepted approach to cancer treatment. Innovation and increased demand for patient-centered care are leading more physicians to want to veer from this one-size-fits-all approach. In these instances, physicians are considering the unique medical history and experience of each patient, as well as diagnostic tests, to recommend a custom-designed treatment path.

Ruth Bader Ginsberg's treatment plan provides a well-known example of this. In 2018, Justice Ginsberg, now a four-time cancer survivor, underwent lung surgery. Some may have considered surgery a non-traditional option in her situation. But science has shown that taking an aggressive approach can be lifesaving, especially for cancers that have spread from their primary location to somewhere else in the body. In short, Justice Ginsberg's experience highlights why it's sometimes necessary to deviate from the standard course of care to do what's best for a specific patient.

Insurers, however, may not see it this way. Health plans are not always set up to allow physicians to provide a curable patient with a curative treatment plan. In fact, public and private insurers alike may use utilization management such as prior authorization and step therapy to discourage personalized cancer treatment approaches. It's

not uncommon for physicians and their staff to spend hours each day on paperwork proving the medical necessity of what they've prescribed their patients.

Diagnostic Testing

Coverage issues are also common with diagnostic testing. Some physicians and geneticists may call for full genomic sequencing to gain a comprehensive picture of their patient's situation. Insurance, however, may limit coverage to a single test. If insurers aren't swayed by the clinician's rationale and opt to deny coverage, patients must assess their capacity to shoulder high out-of-pocket costs to determine which treatment might save their lives.

Unfortunately, clinicians and patients may find themselves in the same situation again and again, as cancers are known to mutate. Each new instance of cancer may require genomic testing to ensure the optimal treatment is used. Even after beating the disease, cancer survivors may require repeated genetic testing in subsequent years. But insurers, if they pay at all, often will pay only once.

Another example of barriers to diagnostics involves the use of liquid biopsies. Liquid biopsies are quick to obtain and minimally invasive; most involve a blood draw, urine sample or mouth swab. In comparison, tissue biopsies require extracting a tissue sample from the cancer tumor or bone marrow. Both methods have advantages and drawbacks. Tissue biopsies are preferred for identifying the type of cancer, whereas liquid biopsies are helpful when a cancer has spread, as it is impractical to conduct a tissue biopsy from each tumor.

Approximately 15% of genes are missed in a liquid biopsy, just as they are with a tissue biopsy, which is why clinicians may order both tests. The results from liquid biopsies are also reported much faster, an important consideration when treating an aggressive cancer. Yet health plans often limit the quantity or type of biopsy they'll cover, making patient-centered cancer care difficult to deliver.

Reimbursement Issues

Both public and private health plans severely limit how much they are



“Reimbursement can dictate timing of tests. Medicare, for example, requires hospitals to wait seven days after a patient’s discharge before sending tissue off for extra testing. Not wanting to delay a patient’s treatment, I started her on chemotherapy. A week later, the test results revealed that an oral drug would have worked for her. Having the test results more quickly would have saved the system money and reduced toxicity for the patient too.”

Alan Marks, MD

willing to reimburse providers for tests and treatments. While some health care providers can absorb a financial hit by offsetting in other areas or because of charitable contributions, most simply can't afford to provide services or treatments at a loss.

Reimbursement issues with genetic testing severely limit physicians' ability to capture the full picture of a patient's health. Meanwhile, the well documented cancer reimbursement saga surrounding CAR T-cell therapy highlights how reimbursement issues impact treatment access as well. The media have comprehensively covered the Centers for Medicare and Medicaid Services' ongoing billing and reimbursement issues.

For patients, reimbursement becomes a matter of treatment access. Without necessary payment,

facilities and health care providers will find themselves unable to provide the diagnostics and cancer-fighting treatments that patients need.

Cost Sharing

Regardless of medication or approach, treating cancer is costly. This reality looms large for many patients, but presents a particular burden for seniors. Most live on a modest, fixed monthly budget and cannot supplement their income to cover medical bills.

In too many cases, patients' course of treatment becomes a matter of what they can afford out of pocket rather than what best meets their personal medical needs. Oral oncolytics, for example, offer many benefits. Patients can take it at home, often with fewer side effects and improved outcomes. But the precision medicine costs patients



"It's difficult to see cost sharing make curative treatments inaccessible for my patients.

I think specifically of an oral therapy that's used to treat breast, colon and other cancers. A breast cancer patient with Medicare would have a 20% co-pay. That's roughly \$600 for every three-week cycle. A younger patient with a high-deductible commercial plan would have to fulfill her entire year's worth of out-of-pocket before getting coverage. And the medication is generic, meaning patients have no co-pay assistance programs to ease their cost burden.

Young or old, Medicare or commercial, generic or brand-name drugs...cost sharing is a real and even life-threatening struggle for too many cancer patients."

Jeffrey VanDeusen, MD, PhD

thousands of dollars out of pocket per cycle, making it out of reach for most. So patients with limited means are forced to use traditional IV chemotherapy because it's covered by their insurance. Never mind that it has more severe side effects, the course of treatment is longer and it requires multiple visits to an infusion center, forcing patients to secure transportation and someone to accompany them for weeks on end.

The conversation around availability and access to cancer treatment is one that must include real figures

about patients' cost sharing. All patients deserve detailed information about what they are expected to pay and when, in plain language that they can understand.

Similarly, as the dialogue about out-of-pocket caps continues, policymakers should consider how increasing financial predictability can benefit patients. The millions of seniors who use Medicare Part D to pay for their prescriptions deserve a less convoluted system where they understand their maximum financial liability.



CONCLUSION

High-profile success stories give hope to the countless Americans touched by cancer. They also highlight how innovative medicine, combined with a more personalized approach to cancer care, can help all Americans – famous or working class, young or old.

All cancer patients want to believe they can overcome the odds. And more will with the steady stream of new treatments, emerging approaches and outside-the-box thinking. The future of cancer treatment is promising. But that promise shouldn't be available only to those with the financial capacity to pay top dollar or travel hundreds of miles to specialty or research centers.

The Cancer Moonshot aimed high. Policymakers and payers now should make adjustments so that innovative, patient-centered care is more broadly accessible to cancer patients, who deserve to reap the rewards of breakthroughs.

REFERENCES

1. National Cancer Institute. Cancer Moonshot. Retrieved from <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative>
2. Immunotherapy to Treat Cancer. Retrieved from <https://www.cancer.gov/about-cancer/treatment/types/immunotherapy>
3. National Cancer Institute. CAR T-Cell Therapy Infographic. Retrieved from <https://www.cancer.gov/about-cancer/treatment/research/car-t-cell-therapy-infographic>
4. National Cancer Institute. With FDA Approval for Advanced Lymphoma, Second CAR T-Cell Therapy Moves to the Clinic. Retrieved from <https://www.cancer.gov/news-events/cancer-currents-blog/2017/yescarta-fda-lymphoma>
5. U.S. National Library of Medicine. What is precision medicine? Retrieved from <https://ghr.nlm.nih.gov/primer/precisionmedicine/definition>
6. National Cancer Institute. Funding for Research Areas. Retrieved from <https://www.cancer.gov/about-nci/budget/fact-book/data/research-funding>

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Please note that the views expressed in this document do not necessarily reflect those of the institutions with which working group members are affiliated.

ABOUT THE ONCOLOGY THERAPY ACCESS WORKING GROUP

The Oncology Therapy Access Working Group is a home for oncologists and other health care providers interested in health policy issues relating to access to cancer therapies.

To learn more, visit allianceforpatientaccess.org/oncology



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