



Outlook on oncology 2023

From biosimilars and virtual reality to technology-driven care, oncology therapy continues to evolve

Optum

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Even after a global pandemic shook the status quo, oncology therapy has forged ahead as one of the most innovative clinical specialties in health care. Despite the hurdles, physicians, patients and the private and public sectors persevered, adapting to a changing landscape, unique engagement techniques and innovative operational processes.

Several key trends will characterize oncology care in 2023. Greater competition and availability of generic and biosimilar medications should offset growing cost concerns while offering patients more treatment options. Notable developments such as new treatment protocols and a novel drug development pipeline will affect physicians and patients alike. Finally, after disruption to in-person settings, technology-driven care delivery and clinical trial strategies may be here to stay.

Here, a detailed analysis of these forecasts, including how certain dynamics will advance oncology care even further.

#1: Innovation continues to accelerate despite industry challenges

A cancer diagnosis can be frightening and life-altering, but more treatment options offer more hope for survival. Deaths from cancer in the U.S. continue to decline among both men and women. In fact, cancer death rates dropped 27% from 2001 to 2020.¹

Fast-tracked approval rates, along with accelerated innovation, speed access to breakthrough therapies. From 2021 to 2022, the U.S. Food and Drug Administration (FDA) issued a total of 23 new oncology drug approvals. This includes a significant number of oral medications, which made up nearly half of all new oncology launches in 2021. As care delivery shifts outside of hospitals and clinics, these medications may be easier to administer, benefitting cancer patients.²

Other notable launches include medications expected to become the new standard for treating metastatic breast cancer with low HER2 protein levels, and the first targeted therapy shown to provide clinically meaningful improvement in progression-free and overall survival compared to standard chemotherapy treatments.³ And a new oral selective estrogen receptor degrader (SERD) approved in 2023 for advanced or metastatic breast cancer may have standard-of-care potential as a monotherapy option.⁴

#2: Targeted therapies enable truly personalized medicine

The increased adoption of biotherapeutics and precision medicine, including medications that enlist a patient's immune system to attack tumors, is one of the most exciting, sustainable trends in oncology. Innovations such as programmed death (PD)-1/L1 checkpoint inhibitors have become the standard of care for patients with non-small cell lung cancer, even being used as first-line therapy.⁵ Other new immuno-oncology treatments, including chimeric antigen receptor (CAR) T-cell agents, may soon replace more chemotherapy as standard second-line treatment.⁶ By targeting tumors based on genetic makeup rather than anatomical location, these therapies are changing the prognosis for many serious, often life-threatening cancers including breast cancer, metastatic non-small cell lung cancer and metastatic melanoma.⁷

For example, new treatment protocols for renal cell carcinoma (RCC) include the use of immunotherapy plus targeted therapy. In fact, nearly all clinical trials with PD-1/L1 inhibitors that began in 2021 investigated their use in combination with other medications, while monotherapy trials have been declining.⁸ Keytruda®, a monoclonal antibody that binds to a PD-1 receptor, is being used in combination with Lenvima® as a more effective treatment for patients than monotherapy alone.⁹ And a combination of Opdivo® and Cabometyx® is also being used for patients who haven't previously had treatment for their advanced RCC.¹⁰

Another immunotherapy has shown promising results in treating lymphomas and some forms of leukemia. Six CAR T-cell agents have been approved since their emergence in 2017, with three of the most recent approvals since 2021 including Carvykti™ (ciltacabtagene autoleucel) and Abecma® (idecabtagene vicleucel), indicated for multiple myeloma as well as Breyanzi® (lisocabtagene maraleucel) to treat large B-cell lymphoma.^{11, 12, 13, 14} These unique medications have exhibited encouraging results within oncology. Many experts are looking toward solid tumors as the next frontier in the evolution of CAR T-cell therapies.¹⁵

Targeted therapies allow oncologists to rethink the traditional standard of care and develop truly personalized protocols for patients. For example, patients who had failed standard Bruton's tyrosine kinase (BTK) inhibitors like ibrutinib can now benefit from pirtobrutinib, which was granted accelerated FDA approval in 2023 for relapsed or refractory mantle cell lymphoma (MCL).¹⁶

As successful as the messenger RNA (mRNA) COVID-19 vaccines have been, researchers have long hoped to use mRNA vaccines to treat cancer. For more than a decade, cancer researchers have been developing a type of treatment known as a personalized cancer vaccine using various technologies including mRNA and protein fragments. Currently, clinical trials are testing mRNA treatment vaccines in people with various types of cancer including pancreatic cancer, colorectal cancer and melanoma.¹⁷ The results look promising.

A glimpse into the future

Innovations in oncology care represent a substantial amount of research and focus on promising improvements in outcomes. Oncology accounts for nearly half (47%) of the biotherapeutic pipeline overall. For hematological cancer, cell therapies represent three out of four next-generation biotherapeutic pipeline medications. And their use in treating solid tumors is driving new therapy development for prostate cancer, non-small cell lung cancer and liver cancer.¹⁸

The incredible promise of precision medicine means managing cancer patients will become more complex. And oncologists specializing in the more than 100 identified types of cancer must stay abreast of the highly targeted therapies and innovations related to their clinical area. It stands to reason they will want to partner with organizations, including specialty pharmacies, that also have this in-depth level of knowledge of their distinct specialty and can help determine which therapies are most appropriate based on an individual's disease state and prognosis, treatment goals and diagnostic results.



#3: Many care interactions stay close to home

The global pandemic prompted new ways of delivering care such as telemedicine which quickly replaced certain in-person clinical interactions. As a result, remote encounters by video applications, patient portals and phone calls grew significantly.

While some aspects of cancer care – such as surgery – require physical encounters, many oncologists have begun adopting telehealth to engage and communicate with patients. One expert estimates that approximately 12% of outpatient oncology visits are conducted via telehealth compared to virtually none before the pandemic.¹⁹ Other aspects of care, including diagnostics, have also incorporated certain in-home components such as blood draws for biomarkers or tumor burden. In response to this trend, the American Society of Clinical Oncology (ASCO) developed Standards and Practice Recommendations for the use of telehealth in oncology.²⁰ These recommendations state that telehealth is a reasonable option for:

- New patient consultations
- Medication prescribing and management
- Discussion of results such as lab and imaging studies
- Supportive care
- Oral medication compliance and adherence evaluations
- Chronic condition management
- Counseling and other treatment or long-term care management interventions

Despite the benefits, remote care has uncovered a unique set of challenges for oncology patients. Now, these people are faced with more responsibility than ever before to stay adherent to therapy, report

side effects or other medication challenges and stay in contact with their care team. Fortunately, technology-driven solutions such as remote monitoring, “smart” pill bottles and high-touch, text-based adherence programs have shown promise in increasing medication adherence and patient satisfaction.²¹ Other studies are evaluating whether artificial intelligence (AI) and virtual reality (VR) can help patients cope with stress and other emotional burdens that accompany a cancer diagnosis.²²

As telehealth and other digital health strategies such as remote monitoring become more integrated into care delivery, patient engagement from the entire oncology care team – including specialty pharmacists – is more valuable than ever. At the same time, using technology-enabled adherence devices, such as “smart” pill bottles, can help patients stay on track with treatment adherence goals.

#4: Cost becomes a bigger concern for patients

Global spending on oncology medications reached \$185 billion in 2021 and is estimated to reach \$307 billion by 2026.²³ In the U.S., growth is expected at a rate of 9–12% as biosimilars, targeted therapies and new medications for rare types of cancer contribute to slightly slower sales uptake compared to prior-year projections.²⁴

Since 2017, seven out of the top 10 cancers tied to most of the spending in developed countries – prostate cancer, breast cancer, melanoma, multiple myeloma, lung cancer, kidney cancer and chronic lymphocytic leukemia (CLL) – each saw double-digit increases in annual spending.²⁵ This increase, according to research firm IQVIA, may be reflective of additional availability of novel therapies, longer treatment durations and more cycles of therapy per patient.²⁶

Unfortunately, these costs can have a downstream effect on patients even when they are insured. ASCO has extensively studied financial toxicity – the detrimental effects of the excess financial strain caused by the high cost of cancer care. Its research has found that many insured patients can be at risk because of the burdens of expensive, long-term treatment in this era of growing cost-sharing. And the longer patients stay on treatment, the more likely it is that financial assistance will run out, putting health outcomes on the line.²⁷

Shrinking insurance benefits, growing out-of-pocket costs and financial difficulties for patients may make high-cost treatments out of reach for some unless they receive additional support. According to the Kaiser Family Foundation, the average individual plan deductible is now \$1,763, and the average premium for family coverage has grown 20% over the last five years.²⁸

These concerns have not escaped the attention of lawmakers. While the COVID-19 pandemic initially delayed many efforts at drug pricing reform, the Inflation Reduction Act, which gave the federal government negotiating power for high-cost medications (among other industry reforms), was signed into law on August 16, 2022. For oncology drug manufacturers, the inflation rebate penalty will limit their revenue growth, and oral cancer therapy manufacturers will be on the hook for a greater portion of drug spending after patients have reached out-of-pocket maximums.²⁹

The effects on the oncology drug pipeline remain to be seen. Manufacturers may raise list prices for new medications or focus on rare indications that affect non-Medicare populations. Regardless, cancer patients will continue to face challenges with treatment affordability among record-high inflation and cost-of-living increases. In an atypical shift, consumer prices have actually outpaced those of medical care. In October 2022, overall prices grew by nearly 8% compared to the prior year, while prices for medical care increased by 5%.³⁰ This relatively high rate of inflation may precede even heftier

health care costs, meaning the 61% of patients who currently struggle to afford their cancer medication will need as much support as possible to access and afford treatment going forward.³¹

As costs continue to rise, working with a specialty pharmacy that can connect patients with financial assistance programs, foundation funds and grants, as well as copay cards and other resources, may be more critical than ever in the months and years to come.

#5: Generics and biosimilars could help with the cost dilemma

There is good news on the cost front thanks to increased competition in drug markets – a key factor in achieving lower prices. Lower-cost oncology alternatives in the form of unbranded generics and biosimilars can help support manufacturer competition while benefitting patients thanks to smaller copays and out-of-pocket expenses in many cases. To reduce the total cost of cancer care, substituting clinically appropriate, lower-cost options such as generic medications and biosimilars has proven effective.

Industry analysts expect that biosimilars will continue to slow global oncology spending, especially in certain hard-to-treat therapy classes such as ovarian cancer.³² Biosimilars are also commonly used to treat brain, breast, cervical, colorectal, kidney, lung and stomach cancers, as well as non-Hodgkin's lymphoma.

Together, biosimilar and generic medicines have cut oncology spending growth in half.³³ Their usage saved patients with cancer nearly \$18 billion in 2021, with a total of \$111 billion in savings over the past 10 years.³⁴ Some of the big medications going off-patent means the potential for lower-cost therapies in the future may help alleviate some of the cost pressures on patients.

Oncology therapies that lost exclusivity from 2020–2022

Brand name	Generic name	Indications
Revlimid® (2022)	lenalidomide	Myelodysplastic syndrome (MDS), multiple myeloma, mantle cell lymphoma (MCL)
Nexavar® (2022)	sorafenib	Hepatocellular carcinoma (HCC), renal cell carcinoma (RCC), thyroid carcinoma, angiosarcoma, gastrointestinal stromal tumor (GIST)
Sutent® (2021)	sunitinib malate	GIST, advanced RCC, pancreatic neuroendocrine tumors (pNET)
Tarceva® (2020)	erlotinib	Advanced non-small cell lung cancer and advanced pancreatic cancer
Tykerb® (2020)	lapatinib	HER2 positive metastatic breast cancer

Oncology biosimilars that received approval from 2020–2022

Reference product	Biosimilar(s)	Indications
Neulasta®	Fylnetra® (pegfilgrastim-pbbk) (2022)	Reduces the chance of infection due to low white blood cell count in people with certain types of cancer (non-myeloid) who receive chemotherapy
	Stimufend® (pegfilgrastim-fpgk) (2022)	
	Nyvepria (pegfilgrastim-apgf) (2020)	
Neupogen®	Releuko® (filgrastim-ayow) (2022)	Treats and prevents febrile neutropenia in patients with cancer undergoing chemotherapy
Avastin®	Almysys® (bevacizumab-maly) (2022)	Metastatic colorectal cancer (mCRC), frontline nonsquamous non-small-cell lung cancer, recurrent glioblastoma, metastatic RCC, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, cervical cancer
	Vegzelma® (bevacizumab-adcd) (2022)	
Rituxan®	Riabni™ (rituximab-arrx) (2020)	Non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL)

Working with a specialty pharmacy that has access to all types of therapies – including emerging therapies in more limited-distribution networks, generics and biosimilars – is an ideal approach.

#6: Oncology care continues to adapt to the lasting effect of COVID-19

The reverberations of the global pandemic had a lasting effect on certain aspects of oncology care, including clinical trial interruptions, delays in surgeries and chemotherapy and fewer screenings leading to late diagnoses (associated with poorer outcomes).³⁵

Oncologists continue to report caseloads that are 20-29% lower than pre-pandemic levels, and regular screenings for common types of cancer were 1-16% below baseline levels through 2021. Community oncologists are also reporting that more of their new patients present with metastatic cancer.³⁶ In the coming years, oncologists may continue to see an influx of patients with later-stage disease, putting greater pressure on clinicians to develop aggressive treatment plans that are both safe and effective.

Even during this difficult time for oncology patients and clinicians, there is good news. A survey from 2020 showed more than half of cancer patients said they want to be more involved in their care decisions as a direct result of the pandemic.³⁷ If this trend, as well as that of virtual care, continues, patient engagement and activation may rise and the need for collaborative care will become more critical than ever.

In addition to their traditional cancer care duties, the enduring effects of COVID-19 mean oncologists now face the added complexity of adjusting certain treatment decisions to keep their patients safe. For example, new options including Paxlovid™ (nirmatrelvir and ritonavir) and other antivirals have shown to be effective in reducing the progression of severe COVID-19, yet are associated with potentially serious drug interactions with multiple cancer therapies, including those for CLL like ibrutinib.³⁸ To address this risk, National Institutes of Health guidelines have recommended that oncologists temporarily discontinue or reduce the dose of cancer therapy for patients prescribed antiviral treatments for COVID-19.³⁹

Because it has changed the way both patients and physicians make decisions, COVID-19 continues to shape the oncology landscape now and likely for years to come.

Given the delays caused by COVID-19, working with specialty pharmacists who may have regular outreach to patients over the phone or via virtual visits may be useful in bridging the gap between office visits and treatments. Plus, specialty pharmacies can provide high-touch care management, flagging drug interactions and even helping cancer patients manage symptoms that increase because of medication adjustments related to COVID-19 treatment.



#7: New technology may change the landscape for the better

There is more good news on the horizon, as emerging technology is being explored to optimize every phase of cancer care, from research to diagnosis and treatment. For example, genomic testing is being used to analyze the mutated genomes of tumor cells. Paired with the latest therapies, this testing makes it possible to use the latest immuno-oncology approaches for patients with many different cancer types. Minimally invasive testing options are also emerging, such as liquid biopsy, which enables analysis of tumors (including circulating tumor cells and DNA) in the patient's blood. Looking further into the future, researchers are even exploring genomic cancer screening for embryos. While somewhat controversial, it could be used to help identify important genetic risk factors for conditions such as breast cancer during fertility treatments.

Practices and researchers are going virtual

In the wider patient care realm, VR systems are helping oncology practices with all types of clinical goals. For example, VR can support patients through the stress and emotional strain that may accompany cancer treatment by placing them in a calming, relaxing environment, such as a virtual beach or cottage in the woods. This technology is also being used to simplify complicated treatment information in a way that engages patients, even children. New VR apps can help patients visualize the location of their tumors and see how their cancer affects normal functioning as well as the potential effect of treatment.

Virtual clinical trials, meanwhile, are an innovation from the pharmaceutical industry and regulators in response to pandemic-related delays. These alternative settings allow companies to overcome the challenges of in-person trials by using electronic monitoring devices and online social media platforms. The most recent data shows just how much of an effect COVID-19 made, including a

46% decrease in new patient accruals and a 24% decrease in newly activated trials between March and May 2020.⁴⁰ Yet from March to May 2021, 3% more patients had been recruited to trials and newly activated trials had increased by 30%.⁴¹ Overall, oncology trial starts reached historically high levels in 2021, up 56% from 2016.⁴² This momentum is crucial to achieving better therapy options for patients with cancer.

Research gets more intelligent

Artificial intelligence helps oncologists and radiologists detect cancers and tumors, diagnose patients and tailor treatment plans by sorting through massive volumes of complex data. This large amount of information is used to “train” the platform about many types of cancer, diagnoses and outcomes and researchers can “teach” the system via their own expertise as well. These goals can improve AI's ability to recognize patterns in clinical data that are too subtle for the human eye to detect.

In one such scenario, AI technology intakes and analyzes tissue samples of people who have already been diagnosed with cancer and combines that with other information, including the results of their biopsies and tests. Using this information, AI can then help determine the type of cancer an undiagnosed patient likely has, how advanced it is, whether it is primary or secondary and other clinical details. This could help dramatically streamline the work effort of oncologists looking to improve diagnosis and treatment for their patients.

As more data is captured across the industry, oncologists are expected to supply greater data as well, especially to payers and manufacturers. Fortunately, some specialty pharmacies can help support this process with respect to data on adherence and outcomes in collaboration with physician partners.

Envisioning the next wave of transformation

From a big-picture perspective, it seems likely that these positive trends will continue to drive exciting, often life-saving options for patients. At Optum® Specialty Pharmacy, our team of passionate oncology experts are always looking ahead to find new ways to provide care in three key areas:

Access

Optum Specialty Pharmacy and Optum® Infusion Pharmacy have access to 76 limited-distribution oncology medications. This means if your patient needs to switch medications over the course of their treatment, they may not have to switch pharmacies.

Affordability

With Optum Savings IQ, patients are matched with financial aid that offers them the lowest out-of-pocket cost. Additionally, biosimilars have the potential to broaden patient access to more affordable treatment options.

Advocacy

We help our patients get and stay on their medication. We provide expert support with programs such as adherence texting, Schedule My Fill, virtual visits, appeals support and a dedicated oncology Risk Evaluation and Mitigation Strategy (REMS) team.



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