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Outlook on oncology 2022

Life-changing clinical and technical advances
with the power to transform oncology care

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From advances in diagnosis — like artificial intelligence (AI)-powered tumor analysis and liquid biopsy — to new first-in-class therapies — oncologists are now able to provide more help, hope and guidance to patients than ever before. Thanks to organizational flexibility in both the public and private sectors, this progress has been forged despite a challenging environment.

Physicians have adapted their practices just as quickly, rethinking the way they engage with patients and modifying their operational processes to bring care closer to home. Finally, as treatment itself becomes more personalized, patient expectations for more collaborative care are growing and may transform the way health care services are delivered.

While the last several years were marked by nearly constant change, the forecast for 2022 shows stabilization in some areas. For example, some patients are returning to the health care system for diagnosis and treatment. Others like the increase in available treatment options. And greater specialization continues to reshape oncology. The following report provides an in-depth look at these trends to determine which will have the most meaningful, lasting effect on people living with cancer, their caregivers and physicians.

#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 United States continue to decline among both men and women. In fact, cancer death rates dropped 27% from 1999 to 2019.[1]

The main driver for this striking statistic is the rapid emergence of new medications with promising efficacy. Many of these new therapeutic agents offer better safety profiles as well as more manageable side effects compared to traditional radiation and chemotherapy agents. In 2020, the U.S. Food & Drug Administration (FDA) issued a total of 20 new oncology drug approvals, including 17 medications and three diagnostic agents, 16 of which are designated as orphan drugs.[2] This is particularly impressive given the challenges government agencies and drug manufacturers faced ensuring adequate staffing and resources during COVID-19.

This list includes approval for medications with a wide range of indications, including several agents for multiple myeloma, breast cancer and gastrointestinal tumors. Among them is a first-in-class therapy for triple negative breast cancer, which to date has had poor outcomes and more limited treatment options. Treatments for patients with small cell lung cancer and thyroid cancer, among many others, were also approved in 2020.

Just a few noteworthy therapies that the FDA approved in 2020:

- **Lumakras™ (sotorasib):** Non-Small Cell Lung Cancer (NSCLC), KRAS-G12C mutation positive
- **Inqovi® (decitabine and cedazuridine):** Myelodysplastic syndrome
- **Onureg® (azacitidine):** Acute myeloid leukemia (AML)
- **Tabrecta® (capmatinib):** Metastatic non-small cell lung cancer (NSCLC) with MET gene mutation
- **Trodelvy® (sacituzumab):** Metastatic triple-negative breast cancer (mTNBC)

#2: Targeted therapies enable truly personalized medicine

The increased adoption of precision medicine, including companion diagnostics, is one of the most exciting, sustainable trends in oncology. These innovations are rapidly becoming the standard of care and many of these new immuno-oncology therapies, particularly programmed death (PD)-1/PD-L1s, are now being used as first-line treatments. By treating 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. For example, Keytruda®, a monoclonal antibody that binds to a PD-1 receptor, is used to treat a wide variety of cancer types and expansion of these indications continued throughout 2021. Another unique type of immunotherapy, chimeric antigen receptor (CAR)-T, is also exhibiting encouraging results within oncology and brings with it the promise of more effective treatment across a range of cancer types including non-Hodgkin's lymphomas.

Such therapies allow oncologists to rethink the traditional standard of care and develop targeted protocols for patients. For example, Pirtobrutinib, indicated for relapsed or refractory B-Cell malignancies, and Asciminib®, FDA-approved for chronic myeloid leukemia in late 2021, are two prime examples of new agents that could transform treatment for these conditions.

Looking into the future

The incredible volume of approvals for oncology medications is being driven by a variety of factors, including drug companies' interest in funding research and a streamlined FDA approval process. Whether this momentum will continue in 2022 is the larger question, given that many of the medications approved in 2021 were based on research and development conducted before COVID-19.

Initially, the global pandemic was expected to cause delays in new trials opening and continuing therapy for certain patients due to ongoing restrictions. However, the pharmaceutical industry and regulators have responded to these challenges with innovations of their own, allowing virtual trials and greater flexibility around clinical trial requirements. In fact, clinical trial starts actually reached a new high in 2020.[3]

Many experts believe that greater innovation is also on the horizon in the areas of both diagnosis and treatment, predicting that immuno-oncology will represent 20% of global oncology spending by 2025.[4] Given oncologists have seen continued delays in individuals seeking care for COVID-19, patients may be in increased need of these therapies.[5] In the coming year, this could mean an influx of patients with later-stage disease, putting greater pressure on oncologists to develop aggressive treatment plans that are both safe and effective.

> Matching the right therapy to each patient has become much more complex because of new therapies, drug classes and indications. The right specialty pharmacy can help oncology practices 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

As the global pandemic increased patient fears and practice shut-downs in early 2020, new ways of delivering care like telemedicine quickly replaced certain in-person clinical interactions. In fact, remote encounters by video applications, patient portals and phone calls grew significantly. By April of 2020, overall telehealth utilization for all types of outpatient care was 78 times higher than it was in February 2020, just two months prior.[6] While the rate of claims for telehealth began to slow and stabilize by late 2021, virtual visits are still a significant driver of industry transformation.[7]

While some aspects of cancer care — like surgery — obviously require physical encounters, many oncologists have begun adopting this new way of engaging and communicating with patients. 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 in 2021 for the use of telehealth in oncology.[8] These recommendations state that telehealth is a reasonable option for new patient consultations, medication prescribing and management, discussion of results like 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.

As telehealth and other digital health strategies like 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, the use of technology-enabled adherence devices, such as "smart" pill bottles, can help patients stay on track with treatment adherence goals.

#4: It's not just pharmacies that are getting more specialized

According to a recent Genentech Trends Report, 49% of oncologists report that over the past five years, they are becoming more specialized in terms of treating specific cancer and tumor types. In this same time period, only 4% report that they are becoming more generalized.[9]

Specialization provides a variety of benefits for both the practice and its patients. This includes allowing the oncology team to cultivate an in-depth knowledge in these specific types of cancer and to become more comfortable treating these patients.

Specialization is especially useful as the process of managing cancer patients becomes more complex; oncologists who specialize can devote more time to staying abreast of only the highly targeted therapies and innovations related to their clinical area. Oncologists certainly have numerous opportunities for specialization. There are more than 100 identified types of cancer, and some, such as breast and lung cancers, have further subtypes that require unique diagnostic tests and treatments.

Given that oncologists are specializing more than ever before, 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.

#5: Cost becomes a bigger concern for patients

Global spending on oncology medications reached $164 billion in 2020 and is estimated to reach $269 billion by 2025.[10] In the U.S., much of the growth in spending — which accounted for $71 billion in 2020 — has been from the growing use of PD-1/PD-L1 drugs as well as the increase in treatments employing small molecule and antibody-targeted agents.[11]

Since 2017, the cancers tied to most of the spending in developed countries — kidney cancer, non-small cell lung cancer, chronic lymphocytic leukemia, melanoma, and multiple myeloma — each saw 20% or more increases in annual spending.[12]

This increase in spending, according to research firm IQVIA, may reflect treatment options with new mechanisms, improved diagnosis rates and longer treatment durations.[13]

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.

In fact, 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 $1,644, up sharply from $826 a decade ago.[14]

These concerns have not escaped the attention of the federal government. While the COVID-19 pandemic initially delayed many efforts at drug pricing legislation, there have been strides in the past year to stem the tide of cost increases. For example, on September 9, 2021, the department of Health and Human Services released the Comprehensive Plan for Addressing High Drug Prices in an effort to make prices more affordable and equitable, promote competition and encourage scientific innovation.[15]

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

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

Fortunately, there is also good news on the cost front. The global generic oncology medications market reached a value of $27.3 billion in 2020.[16] Looking forward, experts expect the market will reach a value of nearly $50 billion by 2026. Industry analysts also expect that biosimilars will help slow global oncology spending, especially in certain therapy classes like colorectal cancer.[17] This helps offset spending growth in other areas like prostate cancer where newer hormone therapies have been approved. Biosimilars are also commonly used to treat brain, breast, cervical, colorectal, kidney, lung, and stomach cancers, as well as non-Hodgkin lymphoma.

Together, biosimilar and generic medicines generated $16 billion in oncology savings in 2020, up from about $13.5 billion in 2019.[18] Some of the big medications going off-patent means lower-cost therapies in the future, which may help alleviate some of the previously mentioned cost pressures on patients.

Below is a list of oncology therapies that have recently lost or will soon lose exclusivity:

Brand name	Generic name	Indications
Afinitor®	everolimus	Certain types of breast, kidney, pancreatic, gastrointestinal and lung cancers
Sutent®	sunitinib	Gastrointestinal and pancreatic cancers
Revlimid®	lenalidomide	Myelodysplastic syndrome (MDS), multiple myeloma, mantle cell lymphoma (MCL)
Thalomid®	thalidomide	Multiple myeloma
Pomalyst®	pomalidomide	Multiple myeloma
Iressa®	gefitinib	Metastatic non-small cell lung cancer

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.

#7: COVID-19 continues to influence care interactions

The reverberations of the global pandemic have had a significant and potentially lasting effect on certain aspects of oncology care, including delays in surgeries, chemotherapy and fewer diagnoses. Oncologists continue to report caseloads that are 26–51% lower than pre-pandemic levels, delays in necessary treatments and screenings at 11–23% below baseline levels.[19] Community oncologists are also reporting that more of their new patients present with metastatic cancer.

As patients begin returning to care, they may find it difficult to get an appointment, face a more advanced diagnosis or have increased logistical challenges. That may be why more than a third of oncologists in the U.S. report that they are giving more support to patients, including spending significant time discussing COVID-19 related topics like booster shots.[20, 21]

In addition to their traditional cancer care duties, oncologists now face the added complexity of trying to keep their patients safe and informed of their unique risks from COVID-19. The enduring effects of the pandemic have directly affected treatment decisions as well. A recent study showed that oncologists stated they would use less chemotherapy, immune checkpoint inhibitors, and steroids because of COVID-19.[22]

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.[23] If this trend continues, patient engagement and activation may rise and the need for collaborative care will become more critical than ever.

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.

#8: 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, the widespread use of genomic testing 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. There are also more minimally invasive testing options 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, virtual reality (VR) systems are also being used to help oncology practices with all types of clinical goals. For example, VR can help patients deal with 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 streamlining new medication research by allowing companies to overcome the challenges of in-person trials. This approach, which often uses electronic monitoring devices and online social media platforms, is especially useful in combatting the delays in trials driven by the COVID-19 pandemic.

The use of virtual trials has the potential to reduce costs, improve recruitment and lower dropout rates. Some experts predict this trend will continue long after the pandemic ends. That's particularly good news given that two thirds of the investments of drug development (in time and money) are tied to clinical trials, which contributes to the cost of any new therapy.

Research gets more intelligent

Artificial intelligence helps oncologists and radiologists to 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 ingests 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.

Large, renowned institutions like Memorial Sloan Kettering Cancer Center and the Cancer Genome Atlas have already made significant strides in these efforts, which are expected to provide incredible insights into cancer pathology. Recent research also supports the accuracy of this approach, including a study that demonstrated the efficacy of AI algorithms in identifying tumor cell types and nuclear breast cancer immunohistochemistry (IHC) marker statuses, including Ki-67, estrogen receptor (ER), and progesterone receptor (PR) status.

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 alleviate this administrative burden by supplying data on adherence and outcomes in collaboration with physician partners.

Envisioning the next wave of transformation

Examining these trends from a big-picture perspective, it seems likely that positive changes like new therapies, technologies and other innovations will continue to drive exciting, often life-saving options for patients. While cost concerns and the upheaval that came with COVID-19 continue to create barriers to care, dedicated oncology team members are finding creative ways to engage with patients and keep them on track with the right treatment. These passionate individuals are also closely collaborating with other industry groups — from non-profits and community resources to specialty pharmacies — for the benefit of patients. As we all look for ways to recover and return to a "new normal," resiliency seems to be the ultimate goal, something we can all learn from the patients who have survived, and often thrived, despite a cancer diagnosis.

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